IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE DIGITEK®
PRODUCTS LIABILITY LITIGATION **MDL NO. 1968**

THIS ACTION RELATES TO:

Campbell v. Actavis, 2:08-cv-01075;
Chambers v. Actavis Totowa, LLC, 2:08-cv-01175;
Konek v. Actavis, Inc., 2:08-cv-1053;
Lange v. Actavis Totowa, LLC, 2:09-cv-00448;
Wilburn v. Actavis Group hf, 2:08-cv-01017;
York v. Actavis Totowa, LLC, 2:09-cv-00544

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

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I. INTRODUCTION

On April 25, 2008, Actavis Totowa LLC initiated a Class I nationwide recall – the type of recall instituted only when there exists a reasonable probability that use of the product will casue serious adverse health consequences or death -- of all strengths of Digitek® (Digoxin Tablets, USP) tablets for oral use ("Recalled Digitek®").[1] Plaintiffs are persons who suffered economic losses from having been prescribed Digitek® (Digoxin Tablets, USP), including those who incurred expenses in light of Defendants' sudden warning of serious health risks posed to those who had ingested Recalled Digitek®.

Plaintiffs' Co-Lead Counsel and the Class Counsel indicated below, pursuant to Pretrial Order No. 16 (as amended), on behalf of Plaintiffs Lorena Ard ("Ard"), Dale Campbell ("Campbell"), Alan Chambers ("Chambers"), Peter Konek ("Konek"), William E. Lange ("Lange"), Judy Whitaker ("Whitaker"), as Executrix on behalf of the Estate of Anna Fight, and Willie Mae Wilburn ("Wilburn"), respectfully submit this memorandum in support of their motion pursuant to Rule 23(c) of the Federal Rules of Civil Procedure to certify a class for economic losses on behalf of the following:

> All persons residing in the United States who purchased Digitek® pursuant to prescription, during the time period when the Recalled Digitek® was manufactured, produced, distributed, sold or otherwise supplied, who suffered economic losses, including, but not limited to, payments for Recalled Digitek®, out-of-pocket expenses for diagnostic testing, medical testing, medical visits, and/or new prescriptions, as a result of having received Recalled Digitek®. Excluded from the Class are Defendants, including any parent, subsidiary, affiliate or controlled person of Defendants and their officers, directors, agents or employees, any judge or judicial

[1] The U.S. Food and Drug Administration ("FDA") classifies a recall as "Class I" where the recall involves: "Dangerous or defective products that predictably could cause serious health problems or death." *See* FDA 101: Product Recalls, attached as Exhibit ("Ex.") A to the Declaration of Fred Thompson in Support of Plaintiffs' Motion for Class Certification ("Thompson Decl.")

officers assigned to this matter, and members of the immediate families of any excluded persons.[2]

As detailed herein, this litigation is ideally suited for class action treatment pursuant to Rule 23(a) and each of the four prerequisites for class certification under Rule 23(a) are satisfied here: (1) numerosity; (2) commonality; (3) typicality; and (4) adequacy of representation. This action also satisfies the core requirements for certification under Rule 23(b)(3) – namely, predominance of common questions of law or fact and the superiority of a class action as a method of adjudication.

Not only do Plaintiffs' claims satisfy the requirements of Rule 23, but class certification is particularly appropriate here where all of class members' claims arise from a course of conduct almost exclusively emanating from a single state, New Jersey, thereby justifying the application of New Jersey's laws to provide a remedy for the purely economic losses suffered by class members. Moreover, this litigation warrants certification because the economic damages suffered by each individual class member are modest and absent the Court certifying a class, millions of consumers will be left with no effective remedy for the harm done to them by Defendants.

These class actions are not personal injury class actions. Distinct from the personal injury/ "mass tort" Digitek claims also before this Court, the present motion arises from movants' consumer class action claims against the manufacturers and distributors of Digitek® and seeks relief for those who incurred foreseeable expenses as a result of the recall and Defendants' related conduct urging customers (the plaintiffs) to stop taking Digitek, replace their

[2] Plaintiffs are not seeking to certify a personal injury or medical monitoring class and do not seek certification of any negligence, negligence per se, or fraud claims. Each of the class definitions in the individual complaints, while utilizing slightly different language, encompass the same theme – persons who suffered economic losses as a result of having been prescribed Digitek and having received the Recalled Digitek. Plaintiffs assert a nationwide class and this motion seeks certification of a nationwide class. As demonstrated, *infra*, *passim*, certification of a nationwide class is appropriate under the circumstances of this case.

medicine, and seek medical consultation. Indeed, Plaintiffs' class claims parallel a recent case from the District Court of New Jersey where the court found certification of a nationwide economic loss class was appropriate, *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 55, 75 (D.N.J. 2009). The putative class members here seek relief for the economic damages they suffered from purchasing Digitek® which was subject to a FDA Class I recall, including the initial price they paid for the product, the cost of a replacement, and any other out-of-pocket losses they incurred, such as the costs of a doctor's visit and medical testing, as a result of the recall.

Unlike the personal injury claims pending before this Court, the class action plaintiffs need not establish that they received or ingested any Excessive Dose Digitek tablets. Their claims arise from the recall, Defendants' conduct surrounding the recall, and the class members' foreseeable actions in, e.g., replacing their medicine or engaging a physician's consultation and/or medical testing. The proposed class meets all the prerequisites of Federal Rule of Civil Procedure 23, including all the requirements of Rules 23(a) and 23(b)(3). This Court's certification of a class action will not only serve to provide a remedy to those who would otherwise be unable to recover their losses but will also serve the larger purposes of this Multidistrict Litigation proceeding by providing a streamlined and efficient method for the resolution of thousands of claims.

II. FACTUAL BACKGROUND

A. THE DRUG - DIGITEK® (DIGOXIN TABLETS, USP)

Digitek® is a trade-name for digoxin, which is derived from the foxglove plant. It is one of the cardiac glycosides, a group of drugs widely used in the treatment of various heart conditions, including heart failure and abnormal heart rhythms such as atrial fibrillation and atrial flutter. It is a commonly used antiarrhythmic agent, used in controlling the heart rate.

Digitek® is a registered trademark of one or more of the Mylan Defendants. Digitek® is distributed by Mylan Pharmaceuticals under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label. Defendants control, directly or indirectly, a material portion of the market in the U.S. for digoxin.

The sale of Digitek® in the United States is regulated by the United States Food and Drug Administration ("FDA"). It was approved for sale and distribution in the United States only in the two following dosages: (i) Digitek® (digoxin tablets, USP) 0.125 mg; and (ii) Digitek® (digoxin tablets, USP) 0.250 mg (although the 2 strengths are sold in various package sizes) ("FDA Approved Dosages"). Both dosages of Digitek® are approved by the FDA only for sale and distribution if the dose contains the labeled amount of digoxin. Digitek® tablets manufactured and distributed with an amount of digoxin in excess of the labeled dose are not approved by the FDA for sale or distribution in the United States ("Unapproved Excessive Dose").

Digoxin has a narrow therapeutic index or maintenance dose range, i.e., the margin between drug effectiveness and drug toxicity. Digoxin toxicity can occur from a single dose or from chronic overmedication. Even a slight overdose with this potent glycoside can cause life-threatening side effects in patients taking the drug. Such adverse effects can include cardiac arrhythmia, ventricular tachycardia or fibrillation, increased (atrial) arrhythmogenesis, and inhibited atrio-ventricular conduction. Additional adverse effects include loss of appetite, nausea, vomiting, diarrhea, low blood pressure, bradycardia, blurred vision, visual disturbances, confusion, drowsiness, and dizziness.

Defendants manufactured and/or distributed Digitek® for the United States market. The manufacturing and production facilities for Digitek® were in New Jersey. All of the Recalled Digitek®, was manufactured and produced at the Actavis Totowa plant in Little Falls, New

Jersey.[3] Similarly, the government inspections that gave rise to the recall all took place in New Jersey.

On or about April 25, 2008, Actavis Totowa LLC initiated the Class I nationwide recall of the Recalled Digitek® due to the fact that Defendants manufactured and sold tablets in an Unapproved Excessive Dose, i.e., with apparently more than approved level of digoxin, in the United States. Numerous reports of illness and injury related to Digitek® have been reported to the FDA and/or to one or more Defendants.[4] Neither the FDA nor Defendants have publicly disclosed how long the defective pills were sold in the U.S. However, Actavis Totowa admits that there were at least 171 batches representing 692.4 million pills, manufactured between April 20, 2006 through February 9, 2008, that were recalled on April 25, 2008.[5] (Defendants only recalled the pills that were within expiration.)

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[3] "All manufacturing operations [for Digitek] occurred at the Actavis Totowa, Little Falls, New Jersey facility." Answers of Defendants Actavis Inc., Actavis Totowa LLC and Actavis Elizabeth LLC to Plaintiffs' First Set of Interrogatories Directed to Defendants ("Defts' Responses to First Set of Interrogatories"), p. 5. *See* Thompson Decl., Ex. B. The Little Falls facility is located at 101 East Main Street, Little Falls, NJ 07424 and is comprised of two buildings. (*See ANDA)*. The Quality Control Laboratory was located at the Little Falls Facility until 2007. "Actavis Totowa began transferring overall quality control lab operations to the Riverview facility in August, 2007. Quality control testing of Digitek at the Riverview facility, including testing of raw materials, blend samples, finished product, and stability testing, began in December, 2007." Answers of Defendants Actavis Inc., Actavis Totowa LLC and Actavis Elizabeth LLC to Plaintiffs' Second Set of Interrogatories Directed to Defendants ("Defts' Responses to Second Set of Interrogatories"), p. 12. *See* Thompson Decl., Ex. D. The Riverview facility is located in New Jersey as is the Taft Road facility where Digitek is packaged. (Actavis 1st Answers to Plaintiffs Interrogatories at p. 5.) *See* Swapan Roychowdhury Depo 110:23-112:16, Thompson Decl. Ex. E (indicating that most of the firm's manufacturing operations and receipt of raw materials occurs at the Little Falls facility; and stating that from January 2008 onward, Actavis Totowa did laboratory testing and some other manufacturing activities at its Riverview Drive facility.)

[4] The FDA 483 inspection form issued after the 01/10/2006 – 02/08/2006 inspection illustrates the repeated failure to investigate and report serious adverse events related to Digitek® including a death that occurred within 2.5 hours of taking the pill. (Observation 1, FDA 483 issued to Actavis Totowa on 02/08/2006, *see* Thompson Decl., Ex. F.) Additionally, seventeen adverse experiences "reported by one nurse in September 2000 were not submitted for atrial fibrillation and lack of effect when taking Digitek® (digoxin) Tablets. The nurse reported that 20 patients were switched to the innovator brand and his/her adverse experiences resolved within three weeks, only 3 reports were submitted." (Observation 4, FDA 483 issued to Actavis Totowa on 02/08/2006, *see* Thompson Decl., Ex. F.)

Defendants' 2004 Annual Report on Digitek® to the FDA dated February 21, 2005, includes a customer complaint concerning a "Thick tablet." (Document labeled ACTAV 005697, *see* Thompson Decl., Ex. G.) The complaint summary says "Tablet was left in the vibrator during the set up of the machine and passed undetected." *Id.*

[5] *See* Defts' Responses to Second Set of Interrogatories, Interrogatory No. 40 (Thompson Decl., Ex. D):

(cont'd on next page)

B. THE FDA'S "GOOD MANUFACTURING PRACTICES"

"Good Manufacturing Practice" is a regulatory guideline imposed by the FDA on all manufacturers of pharmaceutical products to ensure that the products have, among other things, the identity, strength, quality, and purity they are required to have. The FDA's "Good Manufacturing Practice" regulations describe the methods, controls, equipment, and facilities that must be in place for the manufacturing of pharmaceutical products. The Actavis Defendants supposedly verified the adherence of their manufacturing operations in the United States to the FDA's "Good Manufacturing Practice" regulations.[6]

C. THE FDA WARNING LETTERS

1. The August 15, 2006 FDA Warning Letter

Some, if not all, of the Recalled Digitek® was designed, developed, manufactured, produced, sold, marketed, labeled, packaged, dosed, advertised, supplied, and/or distributed from a plant in New Jersey owned by one or more of the Actavis Defendants. Indeed, according to

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There were 171 batches of Digitek® subject to the April 25, 2008 recall; 153 of the batches were actually released to the retail or consumer level and then recalled. A theoretical batch of 0.125 mg Digitek® contains 4.8 million tablets. A theoretical batch of 0.250 mg Digitek® contains 4.2 million tablets. 83 batches of 0.125 mg Digitek, theoretically 398,400,000 tablets, were recalled from the retail and consumer level; 70 batches of 0.25 mg Digitek®, theoretically 294,000,000 tablets, were recalled from the retail and consumer level.

[6] According to the U.S. Government's "Complaint for Permanent Injunction" filed in *U.S.A. v. Actavis Totowa, LLC, Actavis, Inc., corporations and Sigurdur Oli Olafsson, Douglas Boothe, individuals,* Case. 2:08-cv-05656-SDW-MCA, ¶¶11-12 (*see* Thompson Decl., Ex. I), state:

> 11. FDA's five inspections of Actavis Totowa's facilities over the last three years have revealed numerous and recurring violations of the current Good Manufacturing Practice (CGMP) requirements for drugs in violation of the FDCA. FDA inspected Actavis Totowa four times in 2006 and 2007: three times at the firm's Little Falls facility and one time at the firm's Taft Road facility. FDA issued Warning Letters to Actavis Totowa in 2006 and 2007. Most recently, from March 18 through May 20, 2008, FDA inspected Actavis Totowa's new Riverview Drive facility, and again found numerous and significant violations of the DGMP requirements.
>
> 12. FDA's inspections establish that the drugs being manufactured and distributed by Defendants are adulterated within the meaning of 21 U.S.C. §351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with the DGMP requirements for drugs.

Defts' Responses to First Set of Interrogatories, Interrogatory No. 1, "All manufacturing operations (for Digitek®) occurred at the Actavis Totowa, Little Falls, New Jersey facility"[7] and "Digitek was manufactured at the Little Falls facility during the last 5 years." (*Id.* at Interrogatory 18.)

From January 10 through February 8, 2006, the FDA conducted an inspection of Actavis Totowa's facilities in New Jersey. As a result of such inspection, the FDA issued a "Warning Letter" to the Actavis Defendants through Divya C. Patel, President of Actavis Totowa, in Little Falls, New Jersey, concerning their failure to comply with the Federal Food, Drug, and Cosmetic Act and the rules and regulations promulgated thereunder (the "August 2006 Warning Letter"). *See* Thompson Decl., Ex. C.

In the August 2006 Warning Letter, the FDA warned the Actavis Defendants, through Actavis Totowa, that it had failed to comply with FDA reporting and record keeping requirements, failed to file periodic safety reports, and lacked procedures regarding investigations, maintenance of records, and evaluation of adverse events data.

According to the FDA's August 2006 Warning Letter, the FDA inspection revealed, *inter alia*, that: there were six potentially serious and unexpected adverse drug events for products, including digoxin, that were not reported to the FDA, it failed to file periodic safety reports which resulted in at least 26 adverse drug experiences which were never reported, and Actavis had not developed procedures for the surveillance, receipt, evaluation, and report of adverse events.

The August 2006 Warning Letter stated, in particular, *inter alia*:

> Deviations demonstrating your firm's failure to comply with 21 CFR §§ 314.80, 314.98 1, and 310.305, which were observed during the

[7] Defts' Responses to First Set of Interrogatories, Interrogatories Nos. 1 and 4 describe the manufacture and production procedures for Digitek at the Little Falls, New Jersey facility. *See* Thompson Decl., Ex. B. After manufacture, the finished product was shipped to Mylan for distribution. *Id.*

> inspection, include the following: (21 CFR § 314.98 requires applicants holding an approved abbreviated new drug application (ANDA) to comply with certain reporting and record keeping requirements of 21 CFR § 314.80. Thus, deviations demonstrating your firm's failure to comply with 21 CFR § 314.98 are described in relation to 21 CFR § 314.8)
>
> 1) Failure to submit to the Food and Drug Administration (FDA) ADE reports as required by 21 CFR §§ 314.80(c)(1) and 314.98(a) and 310.305(c). Specifically, there were six potentially serious and unexpected adverse drug events dating back to 1999 for products such as Digoxin, . . . that were not reported to FDA.
>
> * * *
>
> 4) Your firm has never filed a periodic safety report as required by 21 CFR 314.80(c)(2) and 314.98(a). The inspection found that your firm is not following procedures that were established for filing periodic safety reports. This failure to submit periodic safety reports has resulted in at least twenty-six ADEs which were never reported to FDA.
>
> 5) Procedures for the surveillance, receipt, evaluation, and reporting of adverse events have not been developed as required by 21 CFR 314.80(b), 314.98(a), and 310.305(a). Specifically, your firm lacks procedures regarding follow-up investigations, adequate completion of the MedWatch form (FDA Form 3500A), maintenance of records to assure timely submission of 15-day reports, and evaluation of adverse event data for serious outcome and event expectedness.
>
> * * *
>
> The specific violations noted in this letter are serious and may be symptomatic of underlying problems. You are responsible for investigating and determining the causes of the violations identified above and preventing recurrence of similar violations.

2. The February 1, 2007 "Revised Warning Letter"

Between July 10 and August 10, 2006, the FDA conducted another inspection of the Actavis Defendants' Little Falls, New Jersey facility. As a result of such inspection, on or about February 1, 2007, the FDA issued a "Revised Warning Letter" to the Actavis Defendants through Actavis Totowa citing, *inter alia*, Actavis Totowa's "significant deviations from the [FDA's] current Good Manufacturing Practice regulations." *See* Thompson Decl., Ex. J.

In the Revised Warning letter the FDA noted several deviations from good manufacturing practices, resulting in the adulteration of drug products manufactured by the Actavis Defendants, that were observed by the FDA during the inspection. The FDA's Revised Warning Letter

included findings that Actavis significantly deviated from good manufacturing practices, failed to adequately investigate and resolve laboratory deviations and out-of-specification test results for drug products, failed to properly document the preparation and testing of samples, and failed to properly analyze drug products. The products affected included digoxin. The Revised Warning Letter stated, in particular, *inter alia*:

> During the inspection, our investigators documented significant deviations from the current Good Manufacturing Practice (cGMP) regulations set forth in Title 21, Code of Federal Regulations, Parts 210 and 211, in conjunction with your firm's manufacture of prescription drug products.
>
> The inspection revealed that drug products manufactured in your facility are adulterated within the meaning of 21 U.S.C. §351(a)(2)(B), Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for their manufacture, processing, packing, or holding do not conform with cGMPs, to assure that such drug products meet the requirements of the Act. The deviations were presented to your firm on a FDA-483, List of Inspectional Observations, at the close of the inspection on August 10, 2006.
>
> The significant observations included, but were not limited to, the following:
>
> 1. Significant deficiencies were found in the operations of your firm's quality control unit, and as a result there is no assurance that many drug products manufactured and released into interstate commerce by your firm have the identity, strength, quality and purity that they purport to possess.
>
> Our investigators observed numerous instances where the quality control unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results involving drug products that ultimately were released for distribution into interstate commerce. Additionally, our investigators uncovered out-of-specification test results in laboratory raw data that were not documented in laboratory notebooks, and found that products were released based on retesting without any justification for discarding the initial out-of-specification test results.
>
> Numerous instances were observed where manufacturing process deviations occurred and in-process specifications were not met, yet there is no indication that action was taken promptly to investigate or to correct the deviations and the products were approved for release and distribution by your quality control unit. Additionally, instances were noted where your firm's quality control unit reviewed and approved test data and

reports that were inaccurate and incomplete, and as such, did not follow established procedures. [21 CFR 211.22(a) and 21 CFR 211.22(d)]

* * *

7. Your firm's cleaning validation studies were found to be inadequate and, as a result, there was no assurance that equipment is adequately cleaned between the manufacture of different drug products. [21 CFR 211.67(b)] For example:

a) Cleaning validation was performed for the process trains without evaluating for sample recovery for numerous products, including: . . . Digoxin Tablets, USP, 0.25mg.

* * *

8. Master and batch production and control records were found to be deficient in that they did not include complete procedures for documenting the collection of samples. Although your firm's procedures require the collection of in-process blend uniformity samples of three times the weight of finished product tablets or capsules, master production records do not require, and batch records do not contain, documentation that the samples are being collected accordingly. [21 CFR 211.186(b)(9) and 21 CFR 211.188(b)(10)]

* * *

[W]e are concerned about the quality of drug products that have been released from your facility under the serious lack of cGMP controls found during the inspection. Your response provides no assurance that the records and conditions of manufacture and testing of each such lot of drug products released and marketed by your firm will be evaluated to assure that the released drug products have their appropriate identity, strength, quality, and purity.

* * *

The issues and violations cited in this letter are not intended to be an all-inclusive statement of violations that exist at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations.

D. THE UNAPPROVED EXCESSIVE DOSE OF DIGITEK® TABLETS

Defendants are pharmaceutical companies engaged in the design, development, manufacture, production, sale, marketing, labeling, packaging, advertising, supply, and/or distribution of Digitek® tablets, including the Digitek® that potentially contained an amount of digoxin different than the dose on the label.

At all times relevant to this action, Defendants knew or should have known that the Recalled Digitek® was not safe for the patients for whom digoxin was prescribed because an improper dose of digoxin can cause serious medical problems, digitalis toxicity and, in certain patients, life-threatening injuries and death. Hence, the Class I recall was issued.

E. THE CLASS I RECALL IN THE UNITED STATES AND DEFENDANTS' FAILURE TO PROVIDE COMPLETE AND ADEQUATE INFORMATION ABOUT THE RECALLED DIGITEK®

On or about April 25, 2008, the FDA announced the Class I Recall of all lots of Digitek®.[8] The FDA announcement, which is available at the FDA's website at http://www.fda.gov/medwatch/safety/2008/safety08.htm#Digitek (*see* Thompson Decl., Ex. L), stated:

> DIGITEK (DIGOXIN TABLETS, USP)
>
> Audience: Cardiologists, family physicians, pharmacists, other healthcare professionals, patients [Posted 04/28/2008] Actavis Totowa LLC notified healthcare professionals of a Class I nationwide recall of all strengths of Digitek, a drug used to treat heart failure and abnormal heart rhythms. The products are distributed by Mylan Pharmaceuticals Inc., under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label. **The product is being recalled due to the possibility that tablets with double the appropriate thickness may contain twice the approved level of active ingredient. The existence of double strength tablets poses a risk of digitalis toxicity in patents with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Several reports of illnesses and injuries**

[8] *See* Paul Galea Depo. 63:15-64:16 (Thompson Decl., Ex. K) (Digitek was taken of the market in a Class 1 recall due to a potential serious issue with the medication).

> **have been reported. Patients should contact their healthcare professional with questions.** (Emphasis added.)

On April 25, 2008, Actavis Totowa LLC issued a press release announcing the Class I Recall, which is identical in all material respects to the FDA announcement. (*See* Thompson Decl., Ex. M.)[9]

F. THE SERIOUS AND LIFE-THREATENING INJURIES FROM DIGOXIN OVERDOSE

Digoxin overdose can cause serious and life-threatening personal injury, even death. Excessive doses of digoxin significantly increase the likelihood that patients will experience the known, serious side-effects and reactions that can result from even approved doses of digoxin.

The Recalled Digitek® was potentially adulterated, defective, unreasonably dangerous and unfit for its intended use. Defendants unnecessarily placed tens of thousands, if not millions, of patients, including Plaintiffs and the members of the Class, at risk of serious injury and/or death and caused them to suffer economic losses, including pharmaceutical or other medical expenses resulting from paying for a drug they could no longer use, ingesting or potentially ingesting a defective drug, and/or medical testing, costs of physician visits, prescription costs, and other expenses.

Defendants knew or should have known about the potential manufacturing and production defects, and negligent sale and distribution of the Recalled Digitek® and had a duty to design, develop, manufacture, produce, sell, market, label, package, dose, advertise, supply,

[9] Defendants have released little additional information about the Recalled Digitek® beyond the information contained in the Press Release set forth above. Defendants have failed to fully, fairly, and adequately inform the medical community and the public, including Plaintiff and the members of the Class of: (i) the identity and number of which lots of Digitek® contained the Unapproved Excessive Dose; (ii) how long Defendants manufactured and produced the Recalled Digitek®; (iii) how long any contaminated drug was supplied, sold, and/or distributed by Defendants; and (iv) the number of reports of illnesses and injuries due to the Recalled Digitek® and the nature and extent thereof.

Defendants' failure to provide Plaintiff and the members of the Class, as well as the public, with complete and adequate information about the Recalled Digitek®, including the foregoing information, is consistent with the safety violations which led the FDA to issue its August Warning Letter and the Revised Warning Letter.

release and/or distribute only safe Digitek® with approved doses of digoxin and doses of digoxin that were consistent with the dose on the label. Defendants knew or should have known that as a consequence of the recall of Digitek®, the ultimate users of the procut had spent money on a product they were advised by Defendants to no longer use, and would likely incur expenses for replacing the product and for related digitalis toxicity screening and medical consultations.

Defendants failed to implement or utilize adequate safeguards, tests, inspections and quality assurance procedures to ensure the accuracy of the strength of Digitek®. Defendants failed to implement or utilize adequate testing, and other procedures, safeguards, and inspections to confirm, monitor and assess the quality, dose and safety of Digitek®. As a result of Defendants' conduct, Plaintiffs and the Class suffered economic losses, including, but not limited to, payments for Recalled Digitek®, out-of-pocket expenses for diagnostic testing, medical testing, medical visits, and/or new prescriptions, as a result of having received Recalled Digitek®.

G. DEFENDANTS' KNEW AND EXPECTED CLASS MEMBERS WOULD SUFFER ECONOMIC LOSSES

Defendants certainly knew and understood that the members of the class suffered and would suffer economic losses due to the Recalled Digitek®. Indeed, the very language of the recall notice, Actavis' press release, as well as the language on Defendants' website, underscores the serious nature of the problems, including illnesses and injuries with the Recalled Digitek®. The language further advises and recommends that class members seek medical help and assistance. (*See* Thompson Decl. Exs. L, M; and §E, *supra*.) Thus, Defendants' very own words advised and motivated class members to incur the very expenses they did. Defendants should be held responsible for the class members' economic losses.

H. MULTIDISTRICT LITIGATION PROCEEDING AND THE PRESENT CLASS ACTION COMPLAINTS

The filing of various civil actions in state and federal courts across the country followed the recall, in which various plaintiffs claimed injuries and losses from alleged exposure to the Recalled Digitek®. On August 13, 2008, the Judicial Panel on Multidistrict Litigation entered an order establishing a multidistrict litigation ("MDL") proceeding in this District consolidating federal Digitek® related actions for joint case management.[10]

Apart from the Master Complaint, numerous separate actions were filed against Defendants and subsequently transferred to this Court by the MDL Panel in which the plaintiffs in those actions asserted class action allegations. During the course of the pre-trial proceedings in this matter, some of those individual class action complaints were dismissed or amended to remove any class action allegations, and at present there are only six actions in the MDL seeking class certification. The six actions were originally filed in New Jersey, West Virginia, Kentucky, and Kansas.

I. THE CLASS PLAINTIFFS ARE APPROPRIATE CLASS REPRESENTATIVES

Named class plaintiffs, Ard, Campbell, Chambers, Konek, Lange, Whitaker, as Executrix on behalf of the Estate of Anna Fight, and Wilburn, are all class examples of appropriate class

[10] In Pre-trial Order # 10, dated January 29, 2009, the Court directed the filing of a Master Complaint. The Master Complaint filed on February, 9, 2009 (which does not allege class claims), contains nineteen counts, only three of which are similar to the present motion for class certification, Count Twelve: Violation of the WVCCPA Count Thirteen: Other UTPA Violations, and Count Seventeen: Unjust Enrichment. Pursuant to the terms of Pretrial Order # 16, the Master Complaint does not "constitute the inception of a new 'case or controversy' in this district," does not "supersede or render moot the pending separate actions that were transferred to this district", does not "toll any applicable statutes of limitations as to any individual Plaintiff," does not "relieve any individual Plaintiff of the requirement to perfect service of process," and is not "deemed automatically included in any particular case." However, certain of the allegations and causes of action in the Master Complaint mirror what is contained in each of the complaints in the class actions presently involved in the MDL.

representatives under Fed. R. Civ. P. 23. They all know they are bringing claims for economic losses and are not prosecuting class claims for personal injury.[11]

Lorena Ard[12]

Ms. Ard, a plaintiff in the York action, lives in Indiana, across the river from Kentucky. *See* Lorena Ard Amended Digitek PFS at p. 13. She has been an Advanced Practice Mental Health RN at Owensboro Medical Health System in Owensboro, Kentucky since 1996. *Id.* All of Ms. Ard's health care providers are located in Kentucky. *Id.* at Appendix, §VII.

Having been using Digoxin for several years, Ms. Ard began using the Digitek brand 0.25 mg tablets in the fall of 2007. *Id*. at p. 4. Soon thereafter, Ms. Ard began feeling extremely ill. *Id*. at p. 3-6. She was extremely fatigued and experienced an irregular heartbeat for many months, which caused her incredible stress as she worried about the possibility that she might die. *Id*. At the time, she had no idea that the Digitek was the cause of her problems. *Id.*

Following numerous visits to the doctors in Kentucky, she underwent a cardiac catheterization at Owensboro (Ky.) Medical Health System. *Id.* at Appendix, §VII. She was transferred to Jewish Hospital in Louisville, Kentucky the next day for admission. *Id.* at Appendix, §VII. Interestingly, the symptoms that had been plaguing Ms. Ard went away while

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[11] In alphabetical order, the 6 actions which assert class allegations are: *Campbell v. Actavis Totowa LLC*, 2:08-cv-01075, originally filed in the District of New Jersey, asserts a nationwide class on behalf of those who suffered economic loss; *Chambers v. Actavis Totowa, LLC*, 2:08-cv-01175, originally filed state court and removed to the District of New Jersey, asserts claims under New Jersey law on behalf of residents of New Jersey who were prescribed and ingested Digitek and who suffered economic losses*; Konek v. Actavis, Inc.*, 2:08-cv-1053, originally filed in the District of Kansas, asserts a nationwide class on behalf of persons who purchased Digitek for personal use; *Lange v. Actavis Totowa, LLC*, 2:09-cv-00448, filed in the Southern District of West Virginia, asserts nationwide class claims on behalf of persons who suffered economic losses from their purchase of Digitek; *Wilburn v. Actavis Group hf*, 2:08-cv-01017, originally filed in the District of New Jersey, asserts a nationwide class; and *York v. Actavis Totowa, LLC*, 2:09-cv-00544, (Plaintiffs Ard and Whitaker) originally removed to federal court in Kentucky, asserts claims on behalf of residents of Kentucky.

[12] Cited pages of the transcript of the deposition of Ms. Ard and Ms. Ard's Amended Digitek Plaintiff Fact Sheet ("PFS") are attached as Ex. N to the Thomspon Decl. Various portions of the transcripts of the Plaintiffs' depositions and fact sheets are redacted as Confidential.

she was in the hospital –and only after being taken off of the Digitek® and placed on Digoxin. *See* Ard Tr. at 46:1-17.

After being discharged from Jewish Hospital in Louisville, Kentucky, Ms. Ard again began taking the Digitek® that she had at home. *Id.* at 47:8-11. The symptoms returned and did not go away until after Ms. Ard learned of the recall and stopped taking Digitek®. *Id.* at 47:17-49:21.

Like numerous other individuals, Mr. Ard has suffered economic damages related to defendants' conduct. In addition to the medical bills incurred in Kentucky for treatment related to digoxin toxicity, Ms. Ard was required to make co-pays to the Kentucky-based providers. *See* Ard PFS at 5. Ms. Ard was also required to expend money for transportation to and from her medical providers. Ms. Ard also has 117 worthless, unused Digitek® tablets for which she has paid. *Id.* Because Ms. Ard suffered economic damages similar to numerous others who reside both in Kentucky and in the border areas, Ms. Ard is perfectly suited to represent the interests of the class.

Dale Campbell[13]

Plaintiff Campbell, a disabled industrial painter, ingested Digitek® pursuant to a physician's prescription and suffered economic losses as a result. Over the course of several years Mr. Campbell ingested one Digitek® pill per day as prescribed by his physician, Dr. Gustav Eles. *See* Campbell Tr. At 80:25-81:13; 38:20-25 (and errata sheet to correct spelling). He was originally prescribed Digoxin by Dr. Eles, but was switched to Digitek at a later date due

[13] Mr. Campbell is a resident of Pennsylvania, but filed his action in the District of New Jersey, asserting claims on behalf of a nationwide class under New Jersey law. Cited pages of the transcript of the deposition of Mr. Campbell, Errata Sheet to the Transcript, and Mr. Campbell's PFS are attached as Ex. O to the Thompson Decl. Mr. Campbell's transcript had been designated as Confidential. For purposes of this motion, Plaintiff is submitting selected excerpts of his transcript on a non-confidential basis. The remainder (as well as redacted portions on these excerpted pages) remains Confidential.

to a change in insurance. *Id.* at 72:20 – 73:3. He regularly had his prescriptions filled at a Rite-Aid pharmacy. *E.g.*, *Id.* at 39:4-10; 72:17-9. Mr. Campbell continued to take Digitek® until Dr. Eles ordered him to "quit taking the pills immediately" after Mr. Campbell telephoned him upon receiving a recall letter from Rite-Aid. *Id.* at 14:25 – 15:7; 20:24 – 21:8; 21:19 – 22:10; 22:23-4; 72:6-11; 89:8-11. Mr. Campbell paid a co-pay each time he filled Digitek® prescription. *Id.* at 77:24 – 78:4.

Mr. Campbell's experience and claims are similar to other members of the Class who were prescribed and ingested the recalled Digitek® during the Class Period. Mr. Campbell's testimony fully demonstrates that he is a prototypical class representative who will more than fairly and adequately represent the class. Mr. Campbell is willing and able to represent the Class in the current action. He decided to file suit after receiving more letters regarding the recall. Id. at 23:24 – 24:7. He knows he represents a class of persons in a similar situation. Id. at 25:20—26:15.[14]

Mr. Campbell is aware of relevant facts in the action, including that the May 2008 recall was due to pills being distributed that were "extra strength." *Id.* at 101:16-20. Mr. Campbell understands that he is representing other members of the Class (those persons who were similarly prescribed and ingested Digitek®). *Id.* at 25:25 – 26:1. Mr. Campbell is seeking to recover his economic (or financial) loss, including the co-pays paid for the Recalled Digitek®, and the

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[14] Mr. Campbell testified:

Q. Do you understand that this lawsuit that you're involved in is a class action?
A. Yes, ma'am.
Q. Do you know what that means?

* * *

A. Yeah, I'm representing the other people that was taking this medicine as well.
Q. Do you understand what your obligations are as a class representative?

* * *

A. To try and recover the losses they had as well.

* * *

Q. Why is it that you decided you wanted to pursue this as a class action and be the representative?
A. To help the other people that took a loss as well.

economic losses suffered by the other members of the Class. *Id.* at 24:15-20; 26:2-6. Mr. Campbell is willing to pursue recovery not only for the co-pays paid by the members of the Class, but also "anything else the court allows for all of the people in the class action suit." *See* Errata Sheet to Deposition Transcript of Dale Campbell.

Moreover, despite Defendants' efforts to undermine this lay-witness during his deposition, he made it clear that he knows he represents others and is seeking to recover "my co-pay for all the medicine and the co-pay for all of the people in the class action suit" (*Id.* at 28:17-9), and he was demonstrably clear that he was not promised anything to serve as a class representative (*Id.* at 28:12-4).

Alan Chambers[15]

Mr. Chambers is an appropriate class representative. He was 56 years old at the time of the recall and was and is a resident of New Jersey. He was prescribed and ingested Digitek® and suffered economic losses (the cost of the Digitek® pills and the cost of medical visits after the recall) as a result of purchasing the recalled Digitek®.

Mr. Chambers took Digitek® .125 mg from about January 23, 2008 to about April 30, 2008. In April 2008, Mr. Chambers went to his Rite Aid Pharmacy to refill his Digitek® prescription and the pharmacy told him that Digitek® had been recalled. Chamber Tr. at 12:4-19, 16:15-22. He understood from the pharmacy that the recall was because the dosage was improper. *Id.* at 13:2-9. At first, since the pharmacy had only basic information about the recall, he left it up to his doctor to contact him as to any alternative to Digitek®. *Id.* at 12:24-25. When that did not happen, Mr. Chambers decided to ask his cardiologist about an alternative to Digitek® at his next routine visit in June 2008, about six weeks away. *Id.* at 13:24-14:9, 17:3-

[15] Mr. Chambers complaint was formerly styled *Palladino v. Actavis, et al*. but Mr. Chambers was substituted. His complaint was initially filed in state court in New Jersey and was removed by defendants to the District of New Jersey, where it was transferred to the MDL. Cited pages of the transcript of the deposition of Mr. Chambers are attached as Ex. P to the Thompson Decl.

18:1. He believed that if there were some problem in waiting, he could rely on the professionalism of his doctor to contact him. *Id.* at 18:2-11. In June 2008, an alternative digoxin was prescribed. *Id.* at 22:5-17.

He understands as a class representative that he would represent residents of New Jersey who took Recalled Digitek®, and who seek compensation for economic losses such as (a) doctor visits, (b) testing ordered, (c) the cost of the Digitek® pills, (d) co-payments. *Id.* at 30:18-31:10,33:4-19, 104:21-106:3. While Mr. Chambers' doctor did not choose to order tests for him (*Id.* at 31:19-21), Mr. Chambers is not in any way in conflict with absent class members whose doctors did order tests. He also suffered economic losses from having to pay a co-pay for his pills. *Id.* at 33:20-23. If he did not have a routine visit scheduled about six weeks after the recall, he would have called his cardiologist for an alternative to Digitek®. *Id.* at 121:2-8. Because many class members may have waited to see their doctor, and because Mr. Chambers would have called sooner but for the upcoming visit, he is an appropriate class representative.

Mr. Chambers also understands his responsibilities as a representative of the class and was not promised anything to be a class representative. *Id.* at 110:19-22.

Peter J. Konek[16]

Mr. Konek is an 80 year old retired realtor with heart problems that required an installed pacemaker/defibrillator. He has taken, and continues to take, heart-rhythm regulating drugs, including five months of Digitek®. Konek PFS at 4. In May 2008, Mr. Konek received the Digitek® recall notices, one from his insurer, Humana, and the other from his pharmacy, WalMart. *Id.* at 7. Included was the information on the refund program. Something about the recall and refund program bothered him. Konek Tr. at 79:1-81:13.

[16] Cited pages of the transcript of the deposition of Mr. Konek and Mr. Konek's PFS are attached as Ex. Q to the Thompson Decl.

Immediately, he called his doctor, who arranged for a substitute prescription for Lanoxin, which he collected that same day. *Id.* at 82:19-83:5. When he collected the Lanoxin, he told the WalMart pharmacist that he "might do something about" this recall, to which the pharmacist responded, "I don't blame you." *Id.* at 65:4-16.

Mr. Konek carefully reread the notices and got angry about the fact that Digitek®'s makers "put a prescription on the market that had no business being there." *Id.* at 79:16-17. He was angry that this altered pill could cause an overdose. *Id.* at 79:23-81:6. Consequently, he called his golfing buddy, Steve Foulston, who referred him to counsel who now represent him. *Id.* at 83:8—84:7.[17] Shortly thereafter, Mr. Konek filed an economic class action in the United States District Court, District of Kansas. He seeks damages, *inter alia*, disgorged ill-gotten gain, equity, punitives, fees/costs, and interest; and alleges claims for violations of, *inter alia*, consumer protection statutes, unjust enrichment, and breaches of express and implied warranties.

Mr. Konek meets the role as class representative. Mr. Konek's damages, amounting to $74.28,[18] reveal that he is a classic example of the small stakes plaintiff for which class actions were intended. He expects nothing special for being a class representative. Konek Tr. at 88:11-14. He also has a better than average understanding of his claims and class action procedures. He knows that counsel, not he, advances the costs of litigation. *Id.* at 89:7-11. He recognizes that Defendants have wronged more than just him. *Id.* at 18:19-25; 19:1-23; and 20:12-24. Mr. Konek came to his opinion of injustice free from taint from exterior sources. *Id.* at 13:14 – 14:10; 57:12-18; and 88:22-24. Finally, he understands that he does not represent those who suffered personal injury (*Id.* at 85:10-19; 86:6-21), or lost wages (*Id.* at 27:15-18).

[17] Counsel are Hutton & Hutton Law Firm, LLC, Wichita, KS.

[18] Per his fact sheet, Mr. Konek paid $20 for five scripts of Digitek®, $46.28 for four scripts of Lanoxin after the recall, and $8.00 for one script of Digoxin. His current script is for Digoxin.

Most importantly, Mr. Konek understands that he has a fiduciary duty to the class as a whole. He recognizes his duty to participate actively in the litigation: he sought and hired counsel (*Id.* at 83:8 – 84:7; 105:25 – 106:6), completed a Plaintiff's Fact Sheet (*Id.* at 106:5-11), provided dates for and attended his deposition (*Id.* at 106:12-18, 22-24), and has agreed to testify at trial as necessary (*Id.* at 106:19-21). And he knows that he is trying to recover on behalf of the whole class, not just for himself: "I feel as though I've got to help them and I'm going to do the best I can for them." *Id.* at 87:16-18. "I just want to see this company punished for what they did and they deserve it." *Id.* at 87:22-24.

William E. Lange[19]

Plaintiff Lange began purchasing and taking Digitek® as prescribed by his physician as early as 2003 and continued purchasing and taking Digitek® until the time of the Recall. Mr. Lange has withdrawn all claims of personal injury and is now seeking to represent the class of Plaintiffs who suffered economic loss. He is an appropriate class representative for the national economic class.

When Mr. Lange received his recall letter, he immediately proceeded to the pharmacy. When he got to the pharmacy the pharmacist did not know anything about the recall so he went home. *See* Lange Tr. at 15:3-9. A few days later the pharmacy called him and told him to bring his pills in because Digitek® had been pulled off the market. *Id.* at 15:10-13. The pharmacist told him the pills had too much or too little active ingredient. *Id.* at 18:2-4. He drove back to the pharmacy and got new pills. *Id.* at 15:14-15. He paid the $10 co-pay on the original Digitek® prescription and the replacement prescription. *Id.* at 22:11-13. His Digitek® prescription was filled in 90-day supplies and he had approximately 35 to 36 pills to exchange for a new prescription. *Id.* at 16:9-12.

[19] Cited pages of the transcript of the deposition of Mr. Lange are attached as Ex. R to the Thompson Decl.

After talking with the pharmacist, Mr. Lange made an appointment with his cardiologist. He talked over the situation with his cardiologist, and no diagnostic tests were performed. *Id.* at 15:15-17, 17:5-23.

The economic injuries that Mr. Lange suffered include the cost of transportation to and from the pharmacy, the prescription costs and the cost of the appointment with his cardiologist. *Id.* at 19:10-20, 21:20-22:13. His injuries and damages are similar to many of the potential class members affected by the recall including the cost of his prescriptions. His situation is also such that it will not prevent him from representing those class members whose doctors ordered diagnostic tests.

Mr. Lange understands that as the class representative he "represent[s] a group of people who have the same feelings as I do." *Id.* at 23:12-22. He also understands that the class is for those with economic injuries only. *Id.* at 24:6-9. He became interested in pursuing a class action after the pharmacist mentioned the possibility of a class to him, before speaking with an attorney. *Id.* at 25:11-26:9; 39:20-40:18. He understands that the obligations of a class representative and that they include being a spokesperson for the class. *Id.* at 41:19-23.

Judy Whitaker as Executrix of the Estate of Anna Fight[20]

Ms. Whitaker represents the estate of her mother, Anna Fight, who died on May 13, 2007. *See* Whitaker as Executrix of the Estate of Anna Fight PFS, at 2. Ms. Whitaker is a resident of Louisville, Kentucky and, at the time of her death, Ms. Fight was a Kentucky resident living in LaGrange, Kentucky. *Id.* Ms. Fight consumed Digitek® .0125 mg which had been prescribed for her by her physician. *Id.* at 5. She experienced nausea, weight loss, fatigue, two strokes and ultimately death because of Digitek®. *Id.*

[20] Ms. Whitaker, as Executrix, is one of the plaintiffs in the York action. Cited pages of the PFS of Ms. Whitaker are attached as Ex. S to the Thompson Decl.

Ms. Whitaker (as the representative of her mother's estate) has suffered economic damages related to the conduct of the defendants. On behalf of her mother, she claims economic damages related to her mother's treatment for the above symptoms, including but not limited to hospitalizations, testing, all travel costs associated with such treatment, and the out-of-pocket expenses associated with such treatment. *See* Whitaker Complaint. Additionally, at the time of her death, Ms. Fight had Digitek® pills for which she had paid. *See* Whitaker PFS at 6. Because Ms. Fight suffered economic damages similar to numerous others, Ms. Whitaker, as Executrix of her Estate, is perfectly suited to represent the interests of the class.

Willie Mae Wilburn[21]

Ms. Wilburn, an Illinois resident, suffered foreseeable financial injuries and losses as a result of the Digitek® recall and defendants' conduct. As her deposition testimony readily demonstrates, she is an eager and willing representative of the class of plaintiffs suffering economic losses.

Ms. Wilburn is the quintessential Digitek® plaintiff. At the time of the recall, Ms. Wilburn had been taking Digitek® (.125 mg.) for many months, pursuant to a physician's prescription. Wilburn Tr. at pgs. 67:18-20. As with many of the putative class members, Ms. Wilburn first learned of the Digitek® recall when her pharmacy called her in April 2008 to advise her of the recall, told her not to take any more and asked that she bring her Digitek® pills in to the store. *Id.* at 14:16-25. Ms. Wilburn asserts class claims for reimbursement of foreseeable expenses, such as hers, in connection with her tablets of Recalled Digitek® and in undergoing medical evaluation and tests in connection with the recall, including physician examination, electrocardiogram, and digitalis blood level testing. *Id.* at 72:15-23.[22] In short,

[21] Cited pages of the transcript of the deposition of Ms. Wilburn are attached as Ex. T to the Thompson Decl.

[22] Ms. Wilburn testified (*Id.* at 128):

(cont'd on next page)

Ms. Wilburn's financial loss claims are typical of those of the proposed class, as they relate to the same drug recall and conduct of defendants.

Furthermore, Ms. Wilburn demonstrated at her deposition that she was interested and actively involved in the prosecution of the Digitek® class claims. She testified, in part, that she: sought out legal counsel after the recall and it was her personal idea to file her Digitek® lawsuit (*d.* at 13:18-23, 18:10-19:25); has consistently spoken with her counsel in this lawsuit for updates and has remained informed on the case through contact with her attorneys (*Id.* at 131:6-23); personally reviewed her lengthy, initial complaint (*Id.* at 134:24-135:8); and knew procedurally that her lawsuit was initially filed in New Jersey and then transferred to another court (*Id.* at 131:24-132:8). She understands her role as a class representative and testified that even if she was offered reimbursement of her own claimed expenses, she would choose to instead pursue the case on behalf of others similarly situated. (Id. at 134:15-23).

III. ARGUMENT

A. PLAINTIFFS SEEK CLASSWIDE RECOVERY FOR FORESEEABLE EXPENSES ATTRIBUTED TO THE NATIONWIDE DIGITEK® RECALL

Defendants' recall notice states, in part:

> Audience: Cardiologists, family physicians, pharmacists, other healthcare professionals, patients….
> The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Several reports of illnesses and injuries have been reported. Patients should contact their healthcare professional with questions.

Q: You mentioned several tests that you had taken shortly after the recall was made known to you, a digoxin blood level, EKG, CAT scan, stress level, et cetera, right?

A: Yes.

Q: Is it your contention that those were—that you incurred expense from those because of the recall and the need to evaluate you, yourself, to see if you had suffered from any ill-impact from a high dose of Digitek?

A: Yes.

See Thompson Decl. Ex. M.

At the time of the recall, persons taking Digitek® were doing so on a regular basis, either daily or ever-other-day. Defendants knew this. Cooperating with the voluntary recall inherently meant that all putative class members should no longer use medicine for which they had paid, and could also require them to replace the Recalled Digitek® with other medication, thereby incurring economic loss for whatever Digitek® tablets they had purchased but could no longer take, and the cost of replacing those tablets. Moreover, pursuant to the very language of the recall, it was foreseeable that class members, concerned for their own health, would seek medical consultation, at some expense, and that those physicians would, in turn, order testing to verify that the patient was not suffering consequences from the warned-of digitalis toxicity.

Defendants anticipated the foregoing types of expenses by putative class members. Notably, although Defendants each promptly posted the full recall notice on their respective websites, none of them made any further representation to soften the recall notice, to assert that those taking Digitek were not at risk, or that medical consultation was not necessary. Defendants' conduct and their nationwide recall justifies nationwide relief to reimburse their customers' recall-related expenses.

B. THIS COURT SHOULD APPLY NEW JERSEY'S CHOICE OF LAW RULES AND APPLY THE SUBSTANTIVE LAW OF NEW JERSEY TO ALL PUTATIVE CLASS MEMBERS' CLAIMS

In determining whether the requirements of Rule 23 are met, this Court is to determine which state or states' substantive law will apply to the prospective class members' claims. District courts exercising diversity jurisdiction must apply the choice of law rules of the forum state. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941). In multidistrict litigation proceedings, the transferee court is to apply the law of the state in which the transferor court is located, including the transferor forum's choice of law rules. *In re Mercedes-Benz Tele Aid*

Contract Litig., 257 F.R.D. at 55; *In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450, 454 (E.D. La. 2006).

In the present case, there are six actions seeking certification of consumer classes that have been transferred to this Court by the MDL Panel. Three of these actions were filed in New Jersey, one in West Virginia, and the remaining two were filed in Kansas, and Kentucky. As detailed in this memorandum, Plaintiffs' motion for class certification seeks redress solely for economic losses suffered by individuals purchasing recalled Digitek®.[23]

An examination of the choice of law rules in each of the jurisdictions where class action cases have been filed reveals that three unambiguously support the application of New Jersey law, whereas Kansas and West Virginia might appear to favor the application of their own law. Nevertheless, given that the substantive provisions of the law of Kansas and West Virginia mirror that of New Jersey with respect to the issues at bar, this Court can apply New Jersey law uniformly or the law of each of the three jurisdictions at issue to justify the certification of a national class. Thus, the application of these state's laws in this manner to support nationwide certification meets the constitutional constraints imposed upon this Court by *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797 (1985) and its progeny, and is consistent with the outcome of an analogous case, *In re Mercedes-Benz*, 257 F.R.D. 46.

1. The Choice of Law Rules of the Four Jurisdictions at Issue

To begin the choice of law analysis, the Court should examine the rules of each of the jurisdictions where class action cases have been brought. New Jersey applies a "most significant relationship" test to determine the choice of law for the causes of action asserted here, violation of the consumer fraud statute, unjust enrichment, and breach of warranty both express and implied. *See P.V. ex rel. T.V. v. Camp Jaycee*, 962 A.2d 453, 460 (N.J. 2008). The "most

[23] Plaintiffs are specifically not seeking certification of any personal injury or medical monitoring claims, and do not seek certification of any negligence, negligence per se, or fraud causes of action.

significant relationship" test is derived from the Restatement (Second) of Conflicts and provides that "[t]he rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties." Restatement (Second) Conflicts of Law § 145 (1971). Under this "most significant relationship" test, in the event of a conflict between the laws of the various states whose law might potentially be applied, the law of the state with the most significant relationship to the claim is applied. *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. at 57.

Kentucky employs an "any significant contacts" test that is very similar to the "most significant relationship test" of New Jersey. *Saleba v. Schrand*, 2009 WL 4111475, at *3 (Ky. Nov. 25, 2009) (citing *Foster v. Leggett*, 484 S.W.2d 827, 829 (Ky. 1972) (holding that in tort cases, "significant contacts-not necessarily the most significant contacts" permit the application of Kentucky law); *Bonnlander v. Leader Nat. Ins. Co.*, 949 S.W.2d 618, 620 (Ky. App. 1996); *Brewster v. Colgate-Palmolive Co.*, 279 S.W.3d 142, 145 n. 8 (Ky. 2009) (applying Kentucky law in an asbestos exposure case because of "significant contacts" with Kentucky even though the plaintiff was exposed when he worked at the defendant's Indiana plant)).

Finally, Kansas and West Virginia apply a traditional *lex loci delicti* choice of law approach, meaning the law of the forum where the injury occurred will be applied by the court. In following the *lex loci delicti* rule, Kansas adheres to traditional choice of law principles largely reflected in the original Restatement of Conflict of Laws (1934). *Miller v. Dorr*, 262 F.Supp.2d 1233, 1238 (D. Kan. 2003) (citing *Raskin v. Allison*, 57 P.3d 30, 32 (Kan. 2002). This rule is well established under Kansas law and the Kansas Supreme Court has rejected the analytical approach which allows the forum court to apply the law of the jurisdiction most intimately concerned with the outcome of the particular litigation. *Id.* (*citing Ling v. Jan's*

Liquors, 703 P.2d 731 (Kan. 1985)). Similarly, under West Virginia law, courts apply the traditional *lex loci delicti* rule to actions sounding in tort; that is, the substantive rights between the parties are determined by the law of the place of injury. *Vest v. St. Albans Psychiatric Hosp.*, Inc., 387 S.E.2d. 282, 283 (W.Va. 1989) (*citing Paul v. National Life*, 352 S.E.2d 550 (W. Va. 1986)). *See also Vass v. Volvo Trucks North America, Inc.*, 315 F. Supp. 2d 815, 817 (S.D. W. Va. 2004).

Thus, in analyzing each of these transferred actions from the perspective of the transferor court, this Court is required to engage in limited – and substantively similar under the particular facts of this case -- choice of law analyses – the "most significant relationship" test, the "any significant contacts" test, and the traditional doctrine of *lex loci delicti*.

2. The Outcome of the Applicable Choice of Law Rules Point to the Application of New Jersey, Kansas, and West Virginia Law

a. The "most significant relationship" and "any significant contacts" tests

The outcome of the first two choice of law tests points unambiguously to the application of New Jersey law. That is, both the "most significant relationship" test and the "any significant contacts" test result in the choice of New Jersey law.

The "most significant contacts" test looks to five main factors derived from the Restatement (Second) of Conflicts: (1) the interests of interstate comity; (2) the interests underlying the field of tort law; (3) the interests of the parties; (4) the interests of judicial administration; and (5) the competing interests of the states. *P.V. ex rel. T.V.,* 962 A.2d at 463. The third and fourth factors are less significant to the choice of law determination in a tort action, whereas the fifth factor is the most important. *Erny v. Estate of Merola*, 792 A.2d 1208, 1271 (N.J. 2002).

As to the first factor – the interests of interstate comity – it "require[s] courts to consider whether application of competing state's laws would frustrate the policies of other interested states." *Fu v. Fu,* 733 A.2d 1133, 1141 (N.J. 1999). A state should only impose its laws on a particular issue if it has a strong policy that will be fostered by the application of the law. *Id.* With respect to the second factor, *i.e.*, the interests underlying the field of tort law, the court is required "to consider the degree to which deterrence and compensation, the fundamental goals of tort law, would be furthered by the application of the state's local laws." *Id.*

With respect to the final but most important factor – the competing interests of the states – the court should consider qualitative contacts that the litigation has with the state's policies and not the quantitative contacts. *Id.* at 1142. The contacts that are most significant to the analysis are: (1) the place where the injury occurred; (2) the place where the conduct causing the injury occurred; (3) the domicile, residence, nationality, place of incorporation and place of business of the parties; and (4) the place where the relationship, if any, between the parties is centered. *Id.*

Here, the facts clearly establish that not only were the most significant contacts with New Jersey, but all the critical contacts were with New Jersey. The principal defendants are headquartered in New Jersey. The manufacturing plants for the Recalled Digitek® are in New Jersey. Indeed, a review of the various warning letters from the FDA shows that it was Actavis's New Jersey manufacturing plant where the failures to follow good manufacturing practices and to comply with FDA reporting requirements occurred. Moreover, defendant Actavis Totowa's responses to Plaintiffs First and Second set of interrogatories make it abundantly clear that New Jersey is the heart of the conduct at issue in every case. All of the Digitek® that was recalled was manufactured at the Actavis Totowa, Little Falls, New Jersey facility. All of the Digitek® manufactured by any of the Defendants during the five years preceding May 2009, was manufactured in New Jersey. Each and every batch of recalled Digitek® that was distributed by

Mylan Pharmaceuticals, Inc., Mylan Bertek Pharmaceuticals, or UDL Laboratories, Inc. came from the Actavis Totowa plant in Little Falls, New Jersey. Actavis' Regulatory Affairs Department responsible for handling regulatory matters is located in New Jersey.[24] Actavis' Medical Affairs Department, which is responsible for processing product complaints and adverse drug events and reporting them to the FDA, is located in New Jersey.[25] The plant inspections by the FDA that resulted in the recall were conducted in New Jersey. In addition, software applications and laboratory data related to Digitek are housed in computers located in New Jersey.[26]

In short, New Jersey is at the heart of the claims.[27]

b. The *lex loci delicti* test of Kansas and West Virginia

The choice of law test of *lex loci delicti* used in Kansas and West Virginia points, unsurprisingly, to the law of each respective state. According to the Kansas Supreme Court, "an action for the recovery of damages for injuries sustained in Kansas which were the result of a negligent act in another state, the liability of the defendant is to be determined by the laws of this state." *Ling*, 703 P.2d at 732. West Virginia follows the same rule.

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[24] *See Terri-Lee Nataline Depo.* 16:19-19:10 (Thompson Decl., Ex. U).

[25] *See Terri-Lee Nataline Depo.* 28:12-29:9 (Thompson Decl., Ex. U).

[26] *See Richard Dowling Depo*. (Thompson Decl., Ex. V).

[27] With respect to the "any significant contacts" test, the Kentucky Supreme Court has indicated that while the basic rule is for a Kentucky court to apply Kentucky law, it should not do so reflexively or in reliance upon any dogmatic rules like *lex loci*. *Foster*, 484 S.W.2d at 829. Instead, in cases, the court should apply Kentucky law if there are valid reasons to do so and if Kentucky has "any significant contacts" with the dispute. *Id.*

Here, the most significant contacts are with the State of New Jersey, not Kentucky. The only contact Kentucky has with the present dispute is that its residents suffered their economic losses presumably while in Kentucky. Instead, all of the underlying conduct giving rise to these economic losses, occurred in New Jersey. New Jersey is where the Defendants' failure to follow good manufacturing practices resulted in the production of adulterated Digitek, is where Defendants failed to keep their records as required by the FDA, is where Digitek was mislabeled, and is where Defendants made the decision to hide all of these facts from consumers, all conducting culminating in the FDA requiring Defendants to initiate a Class I Recall. As such, Kentucky does not have "any significant contacts" with the dispute so as to justify the application of its law to the present case. To hold otherwise would be to reinvigorate the *lex loci* rule that the Kentucky Supreme Court vitiated.

In the present case, the actions of Defendants took place in New Jersey, but resulted in economic injuries where various class members reside. That is, class members suffered economic loss when they were forced to give up previously purchased Digitek®, perhaps purchase a replacement prescription, and/or possibly visit their physician. These injuries would have occurred wherever the class member lived, not necessarily in the State of New Jersey. Accordingly, this simplistic choice of law rule suggests the application of Kansas and West Virginia law in each of those respective jurisdictions.

3. Notwithstanding the Three Choice of Law Tests, This Court Should Apply New Jersey Law to All Putative Class Members' Claims

Even though the choice of law analysis could point to the application of three different states' substantive law, New Jersey, Kansas and West Virginia, this Court can, and under the circumstances of this case should, apply New Jersey law to all the putative class actions presently before it. Indeed, the Court can, consistent with applicable constitutional considerations, apply New Jersey law to certify a national class.

First, substantively, there is no meaningful difference between New Jersey's consumer fraud act and the analogous consumer protection statutes of Kansas and West Virginia. According to the New Jersey Supreme Court, when analyzing claims under the New Jersey Consumer Fraud Act, "there are only three elements required for the prima facie proofs: 1) unlawful conduct by defendant; 2) an ascertainable loss by plaintiff; and 3) a causal relationship between the unlawful conduct and the ascertainable loss." *Bosland v. Warnock Dodge, Inc.*, 964 A.2d 741, 749 (N.J. 2009) (citations omitted). Under Kansas law, the Kansas Consumer Protection Act "gives consumers a private right of action against suppliers who commit deceptive and unconscionable practices. Although the actions upon which a consumer may establish liability under the KCPA sound largely in fraud, a critical element of a common-law fraud action, the intent to defraud, need not be proven." *Haag v. Dry Basement, Inc.*, 732 P.2d

392, 393 (Kan. Ct. App. 1987) (internal citations omitted). *See also Dunn v. A.G. Edwards & Sons, Inc.*, 167 P.3d 387, 2007 WL 2767997, at *4 (Kan. Ct. App. 2007) (internal citations omitted) ("[T]he KCPA does not require a proof of intent to defraud in order to establish a violation. The KCPA also applies regardless of whether a consumer actually was misled or relied upon the deceptive act or practice."). Finally, under West Virginia law, "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful." W. Va. Code, § 46A-6-104. The WCCPA requires only a cognizable injury and a causal connection between that injury and the Defendants' conduct. *Bertovich v. Advanced Brands & Importing, Co.*, 2006 WL 2382273, at *4 (N.D. W. Va. Aug. 17, 2006). The substantive elements of each of these causes of action nearly completely overlap and any differences between them amount to nothing more than variations in language with no substantive import.

Similarly, there is no meaningful difference between the law of New Jersey, Kansas, and West Virginia concerning Plaintiffs' unjust enrichment claims. Under New Jersey law, "[t]here are two basic elements of an unjust enrichment claim. The plaintiff must "show both that defendant received a benefit and that retention of that benefit without payment would be unjust." To establish the injustice, the plaintiff must further "show that it expected remuneration from the defendant at the time it performed or conferred a benefit on defendant and that the failure of remuneration enriched defendant beyond its contractual rights." *D.R. Horton Inc. - New Jersey v. Dynastar Development, L.L.C.*, 2005 WL 1939778, at *18 (N.J. Super. Ct. Law Div. Aug. 10, 2005) (quoting *VRG Corp. v. GKN Realty Corp.*, 641 A.2d 519, 526 (N.J. 1994)). Under Kansas law, the elements of an unjust enrichment claim are: (1) a benefit conferred on the defendant by the plaintiff; (2) an appreciation or knowledge by the defendant of the benefit; and (3) the acceptance or retention by the defendant of the benefit under such circumstances as to make it

inequitable for the defendant to retain the benefit without payment of its value. *Haz-Mat Response, Inc. v. Certified Waste Services Ltd*, 910 P.2d 839 (Kan. 1996). Under West Virginia law, "[a] claim of unjust enrichment generally entails the establishment of three elements: (1) a benefit conferred upon the plaintiff, (2) an appreciation or knowledge by the defendant of such benefit, and (3) the acceptance or retention by the defendant of the benefit under such circumstances as to make it inequitable for the defendant to retain the benefit without payment of its value. *Veolia Es Special Services, Inc. v. Techsol Chemical Co.*, 2007 WL 4255280, at *9 (S.D. W. Va. Nov. 30, 2007).

These elements are virtually identical, and as recognized by the court in *In re Mercedes-Benz*, variations among states in the elements of unjust enrichment do not create actual conflict. "Although there are numerous permutations of the elements of the unjust enrichment cause of action in the various states, there are few real differences. In all states, the focus of an unjust enrichment claim is whether the defendant was *unjustly* enriched. At the core of each state's law are two fundamental elements – the defendant received a benefit from the plaintiff and it would be inequitable for the defendant to retain that benefit without compensating the plaintiff." *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. at 58 (quoting *Powers v. Lycoming Engines*, 245 F.R.D. 226, 231 (E.D. Pa. 2007), vacated on other grounds, 328 F. App'x 121 (3d Cir 2009).

The law governing breach of warranty, both express and implied, is similar in these three jurisdictions, as well. In each jurisdiction there is no requirement that an injured consumer be in privity with the manufacturer of a defective product and each jurisdiction draws from the Uniform Commercial Code in setting forth the requirements to prove such a claim. *See Gonzalez v. Pepsico, Inc.*, 489 F. Supp. 2d 1233, 1243 (D. Kan. 2007); *Louk v. Isuzu Motors, Inc.*, 479 S.E.2d 911, 920 (W.Va. 1996); *Nelson v. Xacta 3000 Inc.*, 2009 WL 4119176, at *6 (D.N.J. Nov. 24, 2009) (citing *Paramount Aviation Corp. v. Gruppo Agusta*, 288 F.3d 67, 73 (3d Cir. 2002)).

Thus, while the choice of law analysis may result in the application of three different state's laws, as a practical matter, the legal issues and substantive rights flowing from those rules are the same. Also from a practical standpoint, the appropriateness of class certification in the cases before this court is not undermined by the need to apply three state's substantive laws. As will be argued in more detail below, the issues of law and fact for each of these claims will be the same and common issues will predominate in a class defined as Plaintiffs request.

Moreover, over twenty years ago in *Phillips Petroleum*, 472 U.S. 97, the Supreme Court confirmed the power of state courts to certify and exercise jurisdiction over nationwide classes, provided that the exercise of that jurisdiction comports with the due process touchstones of class notice, the right to opt out, and a constitutionally permissible choice of law decision. The Supreme Court reaffirmed the vitality of the *Shutts* choice of law standard as the hallmark of constitutional due process and explicitly applied the *Shutts* rule to choice of law decisions by all courts in *Franchise Tax Board v. Hyatt*, 538 U.S. 488 (2003). In *Hyatt*, the Court stated:

> For a State's substantive law to be selected in a constitutionally permissible manner, that State must have a significant contact or significant aggregation of contacts, creating state interests, such that choice of law is neither arbitrary nor fundamentally unfair.

538 U.S. at 494-95, *citing Shutts*, 472 U.S. at 818.

This Court's selection of New Jersey law to govern the claims of the class fully comports with due process not only because New Jersey's contacts and interests are manifest in this case, but also because all or virtually all of the conduct alleged to be tortious occurred in New Jersey. Under these facts, the selection of New Jersey law to a nationwide class is analogous to the trial court's selection of Nevada law to govern the plaintiff's claims in *Hyatt*, a result the Supreme Court affirmed. So long as this Court's choice of law analysis proceeds in fidelity to the *Shutts* contacts/interests criteria, the Supreme Court has recognized that it is constitutionally permissible "that a court can lawfully apply either the law of one State or the contrary law of

another, " 538 U.S. at 496 (citation omitted). As Justice O'Connor, writing for a unanimous Court, concluded:

> In light of this experience, we abandon the balancing-of-interests approach to conflicts of law . . . [and] thus have held that a State need not substitute the statutes of other states for its own statutes dealing with a subject matter concerning which it is competent to legislate.

Hyatt, 538 U.S. at 496 (internal citations and quotations omitted).

Trial courts may properly choose a state's law over its competitors notwithstanding, and indeed because true conflicts exist. *Shutts* and *Hyatt* empower this Court to choose New Jersey law to govern the adjudication of the pivotal questions that are common to the claims of all members of the proposed injury class.

Indeed, other courts faced with similar requests as in the present case have applied a single forum's law to justify nationwide class certification. For example, in the case of *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. at 72, the Court examined each of the class action cases transferred to it by the MDL Panel and applied New Jersey law to certify a national class under New Jersey law. As with the present case, *In re Mercedes-Benz* dealt with consumer fraud and unjust enrichment claims based upon allegations that a manufacturer failed to disclose pertinent known negative information about a product affecting the product's value and utility, causing economic damages to the putative class members. In examining the law of the relevant jurisdictions, the Court concluded that "an examination of the elements of Plaintiffs' two causes of action -- unjust enrichment and consumer fraud -- reveals that virtually all of the legal and factual issues which will be adjudicated at trial are common to the class." *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. at 72.

Similarly, the United States District Court for the District of New Jersey recently certified a national class composed of New Jersey Consumer Fraud Act ("NJCFA") and breach of warranty claims in *Elias v. Ungar's Food Prods., Inc.*, 252 F.R.D. 233 (D.N.J. 2008). There,

"[t]he Court certifie[d] the claims under the NJCFA and for breach of express warranty for the following class: All persons in the United States who purchased Dr. Praeger's Frozen California Veggie Burgers, Tex-Mex Veggie Burgers, Broccoli Pancakes, Potato Pancakes, and Spinach Pancakes from May 30, 2000 through August 31, 2007." *Elias*, 252 F.R.D. at 240. The Court found that despite the possibility of there being different versions of the product "[t]he different versions will not require the fact-finder to consider different defenses or issues other than whether the product packaging misrepresented the fat and caloric content." *Id.* at 239. Further, because there is not a requirement under the NJCFA that the plaintiff prove "that a consumer has actually relied on a prohibited act in order to recover," plaintiffs are only required to "establish the cause nexus element." *Id.* at 239, quoting *International Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co., Inc.*, 192 N.J. 372, 391, 929 A.2d 1076 (N.J. 2007).

Thus, *In re Mercedes-Benz* and *Elias* confirm that application of the New Jersey's Consumer Fraud Act and unjust enrichment law is appropriate to support nationwide certification.

4. Alternatively, The Court Should Apply Choice Of Law Principles To Certify Single-State Only Class Actions In Each Of The Five Jurisdictions At Issue

As the nationwide recall caused a nationwide class of people to incur entirely foreseeable expenses, anything short of nationwide reimbursement of those expenses by Defendants would constitute an unjust savings from their actionable conduct. Nevertheless, assuming, *arguendo*, that the Court concludes that the choice of law result precludes uniform application of these jurisdiction's laws, then Plaintiffs request that the Court certify single-state class actions in the jurisdictions where class action complaints have been filed and also seek leave from the Court to move for certification of other single-state only classes when and if appropriate class action cases are filed in other jurisdictions and subsequently transferred to this Court. In other words, should

the Court conclude that the law of New Jersey, Kansas, and West Virginia cannot be applied to justify national certification allowing all six actions to be treated uniformly as a single class action, then the Court should use each state's choice of law rules and certify classes for each of the states. In the event the Court follows this approach, Movants request the Court grant leave to file supplemental motions for class certification at some point later in these proceedings should any other appropriate class action cases be filed and transferred to this Court by the MDL panel.

C. THE PREQUISITES OF RULE 23 ARE MET AND THE PROPOSED NATIONAL CLASS SHOULD BE CERTIFIED

Plaintiffs request certification of the following nationwide Class:

> All persons residing in the United States who purchased Digitek® pursuant to prescription, during the time period when the Recalled Digitek® was manufactured, produced, distributed, sold or otherwise supplied, who suffered economic losses, including, but not limited to, payments for Recalled Digitek®, out-of-pocket expenses for diagnostic testing, medical testing, medical visits, and/or new prescriptions, as a result of having received Recalled Digitek®. Excluded from the Class are Defendants, including any parent, subsidiary, affiliate or controlled person of Defendants and their officers, directors, agents or employees, any judge or judicial officers assigned to this matter, and members of the immediate families of any excluded persons.

In order for a lawsuit to be certified as a class action under Rule 23, the named plaintiffs must meet the prerequisites of Rule 23(a) and at least one of the subsections of Rule 23(b). *See Gunnells v. Healthplan Servs., Inc.*, 348 F.3d 417, 423 (4th Cir. 2003). Here, Plaintiffs seek certification under Rule 23(b)(3), which requires that common issues predominate over individual ones and that a class action be superior to other available methods of adjudication.

1. Courts In This Circuit Construe Rule 23 Liberally

The practice in this Circuit is to "'give Rule 23 a liberal rather than a restrictive construction, adopting a standard of flexibility in application [that] will in the particular case best serve the ends of justice for affected parties and promote … judicial efficienc[ies]." *See*

Gunnells, 348 F.3d at 424, *quoting In re A.H. Robins Co., Inc.*, 880 F.2d 709, 740 (4th Cir. 1989); *Black v. Rhone-Poulenc, Inc.*, 173 F.R.D. 156, 159 (S.D. W. Va. 1996). In ruling on class certification, the court does not rule on the merits of plaintiffs' claims, although it must carefully consider whether the requirements of Rule 23(a) and (b) have been met. *Brown v. Nucor Corp.*, 576 F.3d 149 (4th Cir. 2009), citing *Gariety v. Grant Thorton LLP*, 368 F.3d 356, 365-67 (4th Cir. 2004). Trial courts have broad discretion to certify a class and may consider factors other than those listed in Rule 23. *Lowery v. Circuit City Stores*, 158 F.3d, 742, 758 (4th Cir. 1998), vacated on other grounds, 527 U.S. 1031, 119 S.Ct. 2388, 144 L. Ed. 2d 790 (1999) (citing *In re A.H. Robins, Co.*, 880 F.2d at 740 (holding it was proper in determining certification to consider whether certification would "foster the settlement of the case with advantage to the parties and with great savings in judicial time and services.")).

2. The Elements of Rule 23(a) Are Satisfied

a. Rule 23(a)'s Numerosity Requirement is Met

Rule 23(a)(1) requires that the class be of sufficient size that joinder of all members is "impracticable." In determining whether joinder is impracticable, a court should analyze the factual circumstances of the case rather than relying on numbers alone. *Cypress v. Newport News Gen. & Nonsectarian Hosp. Ass'n*, 375 F.2d 648 (4th Cir. 1967). Factors to consider are "the estimated size of the class, the geographic diversity of class members, the difficulty of identifying class members, and the negative impact of judicial economy if individual suits were required." *Christman v. American Cyanamid Co.*, 92 F.R.D. 441, 451 (N.D. W. Va. 1981); *see also McGolthlin v. Connors*, 142 F.R.D. 626, 632 (W.D. Va. 1992).

The proposed Class consists of thousands of persons, if not tens of thousands, located throughout the United States. According to Response to Interrogatory No. 40 of Defendants Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC's Responses To Plaintiffs'

Second Set of Interrogatories ("Defts' Responses to Second Set of Interrogatories"), 83 batches of 0.125 mg Digitek®, theoretically 398,400,000 tablets, were recalled from the retail and consumer level; and 70 batches of 0.25 mg Digitek®, theoretically 294,000,000 tablets, were recalled from the retail and consumer level. *See* Thompson Decl. Ex. D. Accepting, *arguendo*, Defendants' admitted numbers, these recalled tablets represent 13.3 million 30-day prescriptions for 0.125 mg Digitek® and 9.8 million 30-day prescriptions for 0.25 mg Digitek®.[28] While some of these tablets may never have reached the consumer level, regardless of how heavily one discounts the number of tablets, it is beyond peradventure that there are sufficient numbers of potential class members to satisfy the numerosity requirement of Rule 23.

In this case, potential class members number in the thousands. Furthermore, Digitek was sold nationwide, so the class contains members from across the nation. Thus, it is apparent that joinder would be impractical. *See Mullen v. Treasure Chest Casino*, LLC, 186 F.3d 620, 625 (5th Cir. 1999) (holding that a class with 100 to 150 members is generally within the range satisfying the numerosity requirement). The numerosity requirement is obviously met.

b. Questions of Law and Fact Are Common To All Class Members

Rule 23(a)(2) requires a showing of the existence of "question of law or fact common to the class." Fed. R. Civ. P. 23(a)(2). In mass tort cases involving a single product or source of toxic exposure endangering many victims, a showing of commonality as to liability satisfies the common question requirement. *See, e.g., In re A.H. Robins Co.*, 880 F.2d 709 (holding common issues dominated any individual claims in litigation involving the Dalkon Shield); *see also In re Copley Pharm., Inc. "Albuterol" Prods. Liab. Litig.*, 158 F.R.D. 485, 492 (D. Wyo. 1994) (finding common issues predominate defendant's liability for the contaminated Albuterol).

[28] Defendants claim in their Defts' Responses to Second Set of Interrogatories, Interrogatory No. 42, that they do not possess any information regarding the number of prescriptions covered by the recall. *Id.*

Common questions of law and fact involving the injuries and damage allegedly caused by Defendants' alleged liability for the negligent design, marketing and labeling exist for all Class Members. These issues are central to the case and establish commonality. Issues common to all Class Members include, for example:

a. Whether Defendants' violated the New Jersey Consumer Fraud Act;

b. Whether the Recalled Digitek® was and is unsafe for use in humans;

c. Whether Defendants manufactured, marketed, distributed, and/or sold a defective product;

d. Whether Defendants designed, manufactured, labeled, packaged, dosed, supplied, distributed, released and sold Digitek® with knowledge that it was a dangerously defective product;

e. How Defendants acted in designing, developing, manufacturing, labeling, packaging, inspecting, dosing, supplying, distributing and selling the Recalled Digitek®;

f. Whether Defendants conducted, either directly or indirectly, adequate dose testing, batch testing or inspections of Digitek®;

g. Whether Defendants had adequate safeguards in place to ensure that they were manufacturing, dosing, distributing, or selling Digitek® that was safe, not misbranded, or adulterated, and which contained only approved doses of digoxin;

h. Whether Defendants conducted, either directly or indirectly, adequate quality control, testing and/or inspection in the manufacturing and production of Digitek®;

i. Whether Defendants failed to give adequate and timely warning of the problems with Digitek®;

j. When Defendants discovered that Digitek® had a dose of digoxin that was inconsistent with the dose stated in the label;

k. When the FDA and public were notified and then the recall implemented;

l. Whether Defendants properly monitored, tested and inspected Digitek® such that earlier detection of the Recalled Digitek® could have occurred;

m. Whether Defendants concealed information about the problems with Digitek® from the FDA, Plaintiffs and the members of the Class;

n. Whether Defendants under-reported adverse events associated with Digitek®;

o. Whether Defendants' conduct in manufacturing, distributing, and/or selling Digitek® fell below any duty owed by Defendants to Plaintiffs and the members of the Class;

p. Whether Defendants breached warranties;

q. Whether the members of the Class are entitled to compensatory damages, and if so, the nature and extent of such damages; and

r. Whether Defendants are liable for punitive and/or exemplary damages and, if so, the amount thereof and how such punitive and/or exemplary damages should be equitably allocated among Plaintiffs and the members of the Class.

Perhaps most important to the recognition that there are common questions with respect to this economic loss class action is Defendants' own recognition, indeed, understanding and recommendation, that consumers would incur economic loss. The recall press release distributed by Actavis Totowa expressly stated, "If consumers have medical questions, they should contact their health care providers." *See* Thompson Decl. Ex. M. Thus, Defendants recognized that consumers not only had incurred economic losses by purchasing Recalled Digitek®, but would

incur additional economic losses as a result of medical visits, new prescriptions, testing, and follow-up.

c. Plaintiffs' Claims Are Typical of the Claims of All Class Members

To satisfy the typicality requirement under Rule 23(a)(3), the "claims or defenses of the representative parties [must be] typical of the claims or defenses of the class." The class representative and class members need not have identical factual and legal claims. Rather, Rule 23(a)(3) "only requires that the representatives' claims be typical of the other class members' claims, not that the claims be identical." *United Bhd. of Carpenters & Joiners, Local 899 v. Phoenix Assocs.*, 152 F.R.D. 158, 522 (S.D. W. Va. 1994); *see also Mick v. Ravenswood Aluminum Corp*. 178 F.R.D. 90, 92 (S.D. W. Va. 1998). "[T]he appropriate analysis of typicality must involve a comparison of the plaintiffs' claims or defenses with those of the absent class members." *Deiter v. Microsoft Corp.*, 436 F.3d 461, 467 (4th Cir. 2006).

Here, the claims of the Plaintiffs and the Class Members arise from a single product and identical conduct as described in both Master Complaint as well as the class complaints– Defendants' course of conduct in the development and marketing of Digitek® and the subsequent recall.[29] The Plaintiffs and the Class Members are similarly aggrieved by Defendants' conduct and all assert essentially identical legal claims. No conflict exists between the claims of the Plaintiffs and the claims of any other Class member that will preclude certification of this Class.

[29] It should be remembered that Defendants issued a press release announcing the Class I Recall, and put the press release and other information on their websites, in which they advised persons who had been prescribed Digitek that they should consult their own physicians. *See*Thompson Decl. Ex. M. Thus, Defendants were certainly well aware that class members not only had suffered economic losses from purchasing Digitek that they were advised they should not longer use upon risk of death, but also would suffer further economic losses from having to spend monies on physician contacts, new prescriptions, tests, etc.

As illustrated by the summaries of the deposition testimony of the plaintiffs and the documents produced, as described, above, each of the proposed class representatives suffered economic losses, either co-pays, or costs for physicians' visits or medical testing and expenses. There is nothing in their situations that makes any of them unique or different from other members of the class.

Plaintiffs anticipate that Defendants will attack factually the typicality of each named Class Plaintiff, claiming that his or her own health issues, histories and idiosyncracies defeat certification. However, as aptly stated in *Boggs v. Divested Atomic Corp.*, 141 F.R.D. 58, 65 (S.D. Ohio 1991), these arguments are unavailing:

> Clearly, people and parcels of real property, like snowflakes, necessarily have different and unique characteristics. The important question is to what extent those differences, when compared to the nature and extent of the shared characteristics of the named plaintiffs' and class members' claims, will defeat the Court's ability to achieve a considerable efficiency through collective adjudication of those claims.

See also Klein v. O'Neal, Inc., 222 F.R.D. 564, 567 (N.D. Tex. 2005) ("Individual variations among class members' claims with respect to individual causation, medical history, general health, extent of injury, or damages, do not defeat typicality, provided that the claims arise from the same events or course of conduct and are based on the same legal theories.")

Further, in order to prosecute their own claims, each class member will be obliged to make similar legal arguments under New Jersey law to establish Defendants' liability. The proposed class representatives have the same incentive to prove Defendants' wrongful conduct underlying their deceptive trade practices, unjust enrichment, and warranty claims. Moreover, the class representatives seek solely monetary damages to compensate them for out-of-pocket losses related to the FDA's Class I Recall of Digitek® arising from Defendants' misconduct. While it is true that the specific amount of damages will differ from person to person, this fact is insufficient to defeat class certification. *See Gunnells*, 348 F.3d at 429 (rejecting "the same

argument made by almost all defendants in mass tort cases: determining damages will require an individualized injury. Courts have routinely rejected this argument, concluding, as we have in previous cases, that the need for individualized proof of damages alone will *not* defeat class certification.").[30] Indeed, this Court recognized as much in denying a motion to compel filed by the PSC regarding Defendants' responses to class certification discovery requests.

In light of the foregoing, the typicality requirement of Rule 23(a)(3) is satisfied here.

d. The Interests of the Class Have Been Adequately Represented

The final requirement of Rule 23(a) requires that "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). This determination requires a two-pronged inquiry: (1) the named plaintiffs must not have interests antagonistic to those of the class; and (2) the plaintiffs' attorneys must be qualified, experienced and generally able to conduct the litigation. *Christman*, 92 F.R.D. at 453.

(1) The Representative Interests Are Not Antagonistic to Those of the Class

This portion of the adequacy of representation requirement tends to merge with the commonality and typicality requirements of Rule 23(a) *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 626 n.20 (1997). Thus, the reasoning discussed above supporting findings of commonality and typicality also supports a finding that the Class representative's interests are not antagonistic to those of the Class. The representative Plaintiffs and each member of the proposed Class have a similar interest in establishing liability against Defendants. Each of the named Plaintiffs has testified during deposition that they suffered out-of-pocket expenses as a direct consequence of the FDA's Class I recall of Digitek® which was precipitated by the

[30] Indeed, this Court recognized as much in denying a motion to compel filed by the PSC regarding Defendants' responses to class certification discovery requests.

wrongful conduct of Defendants. By pursuing this litigation, each representative Plaintiff necessarily advances the common interests of all other Class Members. No conflict of interest exists as all members of the Class would desire to recover damages for any economic injury sustained because of the purchase of Digitek®.

There is nothing to suggest that the representative Plaintiffs have interests antagonistic to those of the absent Class Members in the vigorous pursuit of the Class claims against Defendants. Here, Plaintiffs seek to represent persons who have purchased Digitek®, each of whom was impacted by Defendants' wrongdoing and each of whom has the same interest as Plaintiffs in establishing Defendants' liability and obtaining these damages.

(2) Class Counsel Are Qualified to Represent the Class[31]

The inquiry in to the adequacy of legal counsel focuses on whether counsel is competent, dedicated, qualified, and experienced enough to conduct the litigation and whether there is an assurance of vigorous prosecution. *McGlothlin*, 142 F.R.D. at 633-34. Proposed Class Counsel for the Plaintiff Class have many years of experience in prosecuting complex products liability and class action litigation. *See* Thompson Decl. ¶33 and Ex. W-EE. Plaintiffs' co-counsel are also experienced in class action and other complex litigation. *See* Biographies of Counsel, attached to as Exhibits W through EE to the Thompson Decl. Plaintiffs' counsel are able and willing to fully prosecute this action. *See* Thompson Decl. ¶33. This litigation has been actively and vigorously pursued through voluminous discovery and research. *Id.*

3. The Requirements of Rule 23(b)(3) Are Met

Having satisfied the four requirements of Rule 23(a), the proposed class action must also meet the requirements of at least one of the subsections of Rule 23(b). Under Rule 23(b)(3), a

[31] Plaintiffs propose that the following counsel constitute an Executive Committee: Bell Law Firm PLLC; Motley Rice LLC; Frankovitch, Anetakis, Colantonio & Simon, Wolf Popper LLP; Malkinson & Halpern, P.C; Hutton and Hutton Law Firm LLC; Bahe Cook Cantley & Jones PLC; Morgan and Morgan, P.A., and the Locks Law Firm LLC.

class may be certified only where "questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and … a class action is superior to other available methods for the fair and efficient adjudication of the controversy." Fed. R. Civ. P. 23(b)(3).

a. Common Questions of Law and Fact Predominate Over Any Individual Issues

Here common questions of law or fact predominate over any questions affecting only individual Class Members, satisfying Fed. R. Civ. P. 23(b)(3). The question is "'whether proposed classes are cohesive sufficiently to warrant adjudication by representation.'" *Gariety v. Grant Thornton*, 368 F.3d 356, 362 (4th Cir. 2004) (citation omitted). When examining factual predominance, courts tend to consider defendants' uniform behavior directed toward class members rather than oftentimes irrelevant individual issues impacting class members. On this basis, courts have found factual predominance where class members asserted harm on account of defendant's uniform sale of defective products. (*E.g.*, *Powers* 245 F.R.D. at 238 ("[T]he central liability issues are what and when Lycoming knew about the defects, and what warranties apply. The resolution of these common issues will resolve a significant portion of the case for all class members"); (*Southern States Police Benevolent Ass'n v. First Choice Armor & Equip.*, Inc., 241 F.R.D. 85, 89 (D. Mass. 2007) (defendant's uniform sale of defective bullet-proof vests; Plaintiffs' claims "turn on whether the Zylon® vests were defective, whether the defendants breached the warranties provided to the purported class members and what, if any, damages were sustained by them."); and (*In re Copley Pharm,, Inc.*, 158 F.R.D. at 492 (defendant's uniform sale of contaminated drugs; "The Court concludes the common issues predominate the Plaintiffs' claims for strict liability, negligence, negligence per se, breach of warranties, and the request for declaratory relief."). Thus, class wide liability turns on Defendants' common practices rather than on plaintiffs' behavior. *See, e.g. Newsome v. Up-To-Date Laundry, Inc.*, 219 F.R.D. 356,

365 (D. Md. 2004) ("The class-wide liability phase of this action turns on common employer practices rather than individual employee reactions."))

Here, proof regarding the dangerous propensities alleged of Digitek® is the same for all persons seeking to establish liability against Defendants. As alleged in the various complaints, Defendants distributed Recalled Digitek® from one plant in New Jersey demonstrating a "uniform" distribution and sale of Recalled Digitek®. These core liability issues are involved in the claims of all Plaintiffs and are subject to common proof.

The only issue remaining would be the amount of damages suffered, and it is well settled that differences in the amount of damages to be awarded to each Class member does not preclude Class certification. "Where [] common questions predominate regarding liability, then courts generally find the predominance requirement to be satisfied even if individual damages issues remain." *Smilow v. Southwestern Bell Mobile Sys., Inc*., 323 F.3d 32, 40 (1st Cir. 2003) (citations omitted); *Gold Strike Stamp Co. v. Christensen*, 436 F.2d 791, 798 (10th Cir.1970); 5 James Wm. Moore, Moore's Federal Practice § 23.46[2][a], at 23-208 & n. 11 (3d ed. 1997 & Supp. 2006) (collecting additional cases); *Blackie v. Barrack*, 524 F.2d 891, 905 (9th Cir.1975) ("The amount of damages is invariably an individual question and does not defeat class action treatment.")).

Indeed, the Fourth Circuit recently reiterated that Rule 23 "explicitly envisions class actions with … individualized damage determinations." *Gunnells*, 348 F. 3d at 427-28; *see also Brown v. Cameron-Brown Co.*, 92 F.R.D. 32, 46 (E.D. Va. 1981) (predominance satisfied even without common damages methodology where violation and impact elements were susceptible to common proof).

"As with the commonality and typicality requirements, the predominance inquiry is directed towards the issue of liability." *Nerland v. Caribou Coffee Co.*, 564 F. Supp. 2d 1010,

1035 (D. Minn. 2007), citing *In re Select Comfort Corp. Sec. Litig.*, 202 F.R.D 598, 610 (D. Minn. 2001). "If the liability issue is common to the class, common questions are held to predominate over individual questions." *Id*. at 1035. "Indeed, courts have often granted class certification despite individual differences in class members' damages." *Id*.

Moreover, as discussed above in the choice of law section, the Court can and should apply New Jersey substantive law to the claims of all putative class members. With the application of New Jersey law to all class members' claims, the same legal issues will arise for each class member, specifically, whether Defendants' conduct violates the New Jersey Consumer Fraud Act and justifies recovery under an unjust enrichment theory and breach of warranty. But even if the Court were to apply the law of the three states implicated in the choice of law analysis above (New Jersey, Kansas, and West Virginia), the operative questions of law and fact remain the same. As previously argued, the elements of a consumer fraud act claim, an unjust enrichment claim, and a breach of warranty claim are the same for each of these three states. In determining whether the Defendants are liable to any particular class member under any one of these state's substantive laws the Court would be effectively determining whether Defendant could be held liable under either of the other state's laws.

b. Class Treatment is the Best Method to Achieve Judicial Efficiency

In *Amchem*, the Supreme Court stated that Rule 23(b)(3)'s superiority requirement, like predominance, ensures that resolution by class action will "achieve economies of time, effort, and expense, and promote…uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results." 521 U.S. at 615.

The rule provides four guideposts for courts to use when making a superiority determination: (1) "the interest of members of the class in individually controlling the prosecution or defense of separate actions; (2) the extent and nature of any litigation concerning

controversy already commenced by or against members of the class; (3) desirability or undesirability of or concentrating the litigation of claims in particular forum; (4) the difficulties likely to be encountered in management of class action." Fed. R. Civ. P. 23 (b)(3).

This case satisfies the superiority requirement. Having this case proceed as a class action will achieve economies for both the litigants and the Court. A class action also significantly reduces the overall costs of complex litigation, allowing plaintiffs' attorneys to pool their resources and requiring defendants to litigate all potential claims at once, thereby leveling the playing field between the two sides. *In re "Agent Orange" Prod. Liab. Litig.*, 597 F. Supp. 740, 842 (E.D.N.Y. 1984). In contrast, if certification of this Class were denied, litigating the similar issues in individual lawsuits would consume many more judicial resources than addressing them at a single blow in these consolidated class actions. *In re A.H. Robins*, 880 F.2d at 742. Requiring individual Class Members to file their own suits would cause unnecessary, duplicative litigation and expense, with parties, witnesses and courts required to litigate time and again the same issues, possibly in different forums.

Absent the class procedure, many Class Members may be effectively foreclosed from pursuing their claims. The Supreme Court has repeatedly recognized that class actions are often the only means for assuring that defendants that have harmed consumers will not benefit from their unlawful conduct simply because of the magnitude of the misconduct and aggregated harm compared to the small magnitude of individual harm. The individual harm is often too minimal to bear high costs of "solo" litigation. Without the class action device, thousands of plaintiffs likely would be denied their day in court. The Supreme Court has adhered to the principle stated in *Amchem* for over 20 years, declaring in *Deposit Guaranty Nat'l Bank v. Roper*, 445 U.S. 326, 339 (1980), "[w]here it is not economically feasible to obtain relief within the traditional

framework of multiplicity of small individual suits for damages, aggrieved persons may be without any effective redress unless they may employ the class-action device."

(1) Class Members' Interests In Individually Controlling Their Suit

The first factor courts consider for superiority is the class members' interests in controlling their own suit. Traditionally, courts have looked to the relative size of class members' claims to determine whether class members would want to individually control their own suit. *See In re Tetracycline Cases*, 107 F.R.D. 719, 732 (W.D. Mo. 1985) (finding that the amount of damages claimed by each individual clamant was relatively small and, thus, that class members had little interest in controlling their own litigation).

It is likely there are many class members who either have not sought out counsel or have not been able to locate an attorney to take their case due to the relatively low value of their cases. Plaintiffs' proposed class will "level the playing field" for these class members who cannot ever be expected to litigate their individual case against a multi-national corporations like Defendants.

(2) The Extent of Existing Litigation

The advisory committee notes seem to indicate that this factor is a derivative of the previous factor. (Fed. R. Civ. P. 23 Advisory Committee Notes 1966 Amendment). Here many of the "known" class members have already filed a suit against Defendants.

(3) This Forum Is Appropriate To Adjudicate This Controversy

This factor weighs in favor of class certification. 2 Conte & Newberg on Class Actions (4th ed. 2002) states that this factor is generally looked in terms of judicial economy, "an approach that should usually support a class action for the obvious reason that it is more economical to have one suit than several." 2 Conte & Newberg, at § 4:31. These authors go on to state that "[i]n the class action context, the desirability of concentrating claims in a particular

forum is relevant only when other class litigation has already been commenced elsewhere." *Ibid.* Here, class counsel is aware of no other class actions pending which encompass the claims of these putative class members.

c. Plaintiffs' Proposed Class Is Manageable

There are no impediments to prosecution of the class claims. There is no difficulty in identifying members of the Class and the size of the Class is manageable. Indeed, trial of class issues will be a much more efficient procedure for the resolution of economic loss claims.

(1) The Class is Ascertainable

Here, the class is readily ascertainable. Class members must have been prescribed Digitek® and had a prescription filled. So, records are available to demonstrate their purchases in any claims process. Similarly, to the extent that some class members incurred economic losses from having physician visits, medical testing, and subsequent prescription replacements, records will clearly establish the amounts involved and can be submitted in any claims process.[32]

In *Hammond v. Powell*, the Fourth Circuit observed that plaintiff had alleged an identifiable class where she "adequately delineated" a class alleging "all citizens of South Carolina whose personal property ha[d] been subjected to 'claim and delivery' and . . . whose personal property would be claimed and delivered during the pendency of the federal action," without the need for providing class members' names, addresses, or other individualized information. 462 F.2d 1053, 1055 (4th Cir. 1972). "An identifiable class exists if its members can be ascertained by reference to objective criteria." *In re Wal-Mart Stores, Inc. Wage & Hour Litig.*, 2008 U.S. Dist. LEXIS 14756, at *16 (N.D. Cal. Feb. 12, 2008). "'A class is ascertainable

[32] Any argument from Defendants that the class is not ascertainable would be sheer sophistry. The maximum parameters for the class have already been ascertained by defendants since they sent out recall notices. Pharmacies have records of the persons to whom they distributed the recall letters (indeed, several of the named plaintiffs received such letters), and defendants have or can obtain records with respect to those persons who submitted their pills pursuant to defendants' instructions in the recall notice. Thus, this is not a case where someone went into a store and purchased an off the shelf product and has no record or way of proving that he made the purchase.

if it identifies a group of unnamed plaintiffs by describing a set of common characteristics sufficient to allow a member of that group to identify himself or herself as having a right to recover based on the description.'" *Moreno v. Autozone, Inc*., 251 F.R.D. 417, 421 (N.D. Cal. 2008) (citation omitted) (stating that "there is nothing particular about Plaintiff's definition that suggests prospective class members will be unable to identify whether they meet the class definition, where the class was defined as: "all former California employees, whose employment with AutoZone ended within the applicable statutory period prior to the filing of this action and who did not receive all wages when due as required by California law." *Id*. at 420.)

The class is sufficiently ascertainable here because the proposed class definitions include persons who were prescribed and purchased Recalled Digitek®, and like plaintiffs, suffered economic loss.

(2) The Size of the Class is Manageable

While the class may be large in number, there is nothing that renders it unmanageable simply due to its size. Further, as detailed in the choice of law analysis above, the Court can and should apply the law of New Jersey. Even if the Court were not inclined to exercise its constitutionally permissible power to apply New Jersey's substantive law to each action, the Court would still need only apply three states' substantive law – that of New Jersey, Kansas and West Virginia. This is not an unmanageable task. Far from it, the substance of each of these states' laws is so similar that when applied to this case, there would be no meaningful differences in the legal and factual issues arising under each of them. In such a situation, the Court could use a unified jury instruction for all three states' laws, for instance, in determining Defendants' liability to class members. Similarly, applying three states' laws would not add any additional administrative burdens or otherwise interfere with a claims administrator's ability to properly

allocate relief once liability were established. In short, the choice of law issues in the present class certification motion are straightforward and manageable.

D. PROPOSED CLASS COUNSEL MEET THE REQUIREMENTS OF RULE 23(g)

As indicated above, Plaintiffs propose a counsel structure to manage the class litigation. The firms have long-standing experience in class litigation. *See* the firm resumes attached as Exhibits W through EE to the Thompson Declaration. They satisfy Fed. R. Civ. P. 23(g).

E. IN THE ALTERNATIVE TO A SINGLE NATIONAL CLASS, THE COURT SHOULD CERTIFY SINGLE-STATE ONLY CLASSES IN THE JURISDICTIONS WHERE THESE ACTIONS HAVE BEEN BROUGHT

As detailed above, each of the prerequisites to class certification under Federal Rule of Civil Procedure 23(a) and (b)(3) has been satisfied. However, in the event that the Court should find it problematic to apply a single state's laws, i.e., the law of New Jersey, to class members residing throughout the country, Plaintiffs request the Court to certify the following single state classes in each of the following cases:

Campbell v. Actavis Totowa LLC, 2:08-cv-01075; *Chambers v. Actavis Totowa*, LLC, 2:08-cv-01175; and *Wilburn v. Actavis Group hf*, 2:08-cv-01017:

> All persons residing in the State of New Jersey who purchased Digitek® pursuant to prescription, during the time period when the Recalled Digitek® was manufactured, produced, distributed, sold or otherwise supplied, who suffered economic losses, including, but not limited to, payments for Recalled Digitek®, out-of-pocket expenses for diagnostic testing, medical testing, medical visits, and/or new prescriptions, as a result of having received Recalled Digitek®. Excluded from the Class are Defendants, including any parent, subsidiary, affiliate or controlled person of Defendants and their officers, directors, agents or employees, any judge or judicial officers assigned to this matter, and members of the immediate families of any excluded persons.

Konek v. Actavis, Inc., 2:08-cv-1053:

> All persons residing in the State of Kansas who purchased Digitek® pursuant to prescription, during the time period when the Recalled Digitek® was manufactured, produced, distributed, sold or otherwise supplied, who suffered economic losses, including, but not limited to, payments for Recalled Digitek®, out-of-pocket expenses for diagnostic testing, medical testing, medical visits, and/or new prescriptions, as a result of

> having received Recalled Digitek®. Excluded from the Class are Defendants, including any parent, subsidiary, affiliate or controlled person of Defendants and their officers, directors, agents or employees, any judge or judicial officers assigned to this matter, and members of the immediate families of any excluded persons

Lange v. Actavis Totowa, LLC, 2:09-cv-00448:

> All persons residing in the State of West Virginia who purchased Digitek® pursuant to prescription, during the time period when the Recalled Digitek® was manufactured, produced, distributed, sold or otherwise supplied, who suffered economic losses, including, but not limited to, payments for Recalled Digitek®, out-of-pocket expenses for diagnostic testing, medical testing, medical visits, and/or new prescriptions, as a result of having received Recalled Digitek®. Excluded from the Class are Defendants, including any parent, subsidiary, affiliate or controlled person of Defendants and their officers, directors, agents or employees, any judge or judicial officers assigned to this matter, and members of the immediate families of any excluded persons

York v. Actavis Totowa, LLC, 2:09-cv-00544:

> All persons residing in the State of Kentucky who purchased Digitek® pursuant to prescription, during the time period when the Recalled Digitek® was manufactured, produced, distributed, sold or otherwise supplied, who suffered economic losses, including, but not limited to, payments for Recalled Digitek®, out-of-pocket expenses for diagnostic testing, medical testing, medical visits, and/or new prescriptions, as a result of having received Recalled Digitek®. Excluded from the Class are Defendants, including any parent, subsidiary, affiliate or controlled person of Defendants and their officers, directors, agents or employees, any judge or judicial officers assigned to this matter, and members of the immediate families of any excluded persons

For all of the reasons set forth above, each of these proposed single-state only class actions meet the requirements of Rules 23(a) and 23(b)(3). Specifically, based upon the volume of pills subject to the Class I recall, there are more than sufficient numbers of class members residing in each jurisdiction to meet the numerosity requirements of Rule 23(a)(1). The common questions of law and fact outlined above are also present in each of these single-state only classes, and the typicality analysis set forth above remains the same, as well. With respect to the "adequacy" prong of Rule 23(a)(4), the creation of single-state classes will not create antagonism between class members; if anything, it could increase the homogeneity between class members and the putative class representatives. Plaintiffs request that the same class counsel be designated as class counsel for each of these single-state only classes so that the adequacy of

counsel prong would be satisfied. Finally, the requirements of Rule 23(b)(3), "predominance" and "superiority," are met through single-state classes in the event that the Court is unwilling to certify a single national class.

Lastly, should the Court not certify a nationwide class based upon the application of New Jersey law, Plaintiffs request the Court grant them leave to file supplemental motions for class certification at some point later in these proceedings should any other appropriate class action cases be filed and transferred to this Court by the MDL panel.

IV. CONCLUSION

For the reasons set forth above and in the accompanying documents, this Court should certify the class, appoint Ms. Ard, Messrs. Campbell, Chambers, Konek, and Lange, Ms. Whitaker, as Executrix on behalf of the Estate of Anna Fight, and Ms. Wilburn as the class representatives; and appoint the following counsel as class counsel: Bell Law Firm PLLC; Motley Rice LLC; Frankovitch, Anetakis, Colantonio & Simon, Wolf Popper LLP; Malkinson & Halpern, P.C; Hutton and Hutton Law Firm LLC; Bahe Cook Cantley & Jones PLC; Morgan and Morgan, P.A., and the Locks Law Firm LLC.

Dated: January 20, 2010

Respectfully submitted,

On Behalf of the Plaintiffs' Steering Committee

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